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Presidential Documents

Title 3—

The President

Memorandum of March 13, 2020

Expanding State-Approved Diagnostic Tests

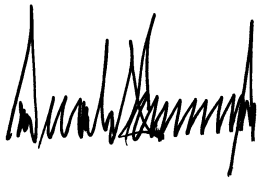
Memorandum for the Secretary of Health and Human Services

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

It is the policy of the United States to take proactive measures to prepare for and respond to public health threats, including the public health emergency involving Coronavirus Disease 2019 (COVID–19), which was declared by the Secretary of Health and Human Services (the ''Secretary'') on January 31, 2020, pursuant to section 319 of the Public Health Service Act (42 U.S.C. 247d). Our response must include heightened coordination among Federal, State, local, and tribal agencies, and we must offer States the flexibility they need to care for their citizens. In accordance with this principle, the Food and Drug Administration, in coordination with the State of New York, allowed the State flexibility in expediting State-approved COVID–19 testing.

Should additional States request flexibility to authorize laboratories within the State to develop and perform tests used to detect COVID–19, the Secretary shall take appropriate action, consistent with law, to facilitate the request.

You are authorized and directed to publish this memorandum in the *Federal Register*.



THE WHITE HOUSE,
Washington, March 13, 2020

[FR Doc. 2020–05793
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Billing code 3295–F0–P

Presidential Documents

Proclamation 9994 of March 13, 2020

Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID–19) Outbreak

By the President of the United States of America

A Proclamation

In December 2019, a novel (new) coronavirus known as SARS–CoV–2 (''the virus'') was first detected in Wuhan, Hubei Province, People's Republic of China, causing outbreaks of the coronavirus disease COVID–19 that has now spread globally. The Secretary of Health and Human Services (HHS) declared a public health emergency on January 31, 2020, under section 319 of the Public Health Service Act (42 U.S.C. 247d), in response to COVID–19. I have taken sweeping action to control the spread of the virus in the United States, including by suspending entry of foreign nationals seeking entry who had been physically present within the prior 14 days in certain jurisdictions where COVID–19 outbreaks have occurred, including the People's Republic of China, the Islamic Republic of Iran, and the Schengen Area of Europe. The Federal Government, along with State and local governments, has taken preventive and proactive measures to slow the spread of the virus and treat those affected, including by instituting Federal quarantines for individuals evacuated from foreign nations, issuing a declaration pursuant to section 319F–3 of the Public Health Service Act (42 U.S.C. 247d–6d), and releasing policies to accelerate the acquisition of personal protective equipment and streamline bringing new diagnostic capabilities to laboratories. On March 11, 2020, the World Health Organization announced that the COVID–19 outbreak can be characterized as a pandemic, as the rates of infection continue to rise in many locations around the world and across the United States.

The spread of COVID–19 within our Nation's communities threatens to strain our Nation's healthcare systems. As of March 12, 2020, 1,645 people from 47 States have been infected with the virus that causes COVID–19. It is incumbent on hospitals and medical facilities throughout the country to assess their preparedness posture and be prepared to surge capacity and capability. Additional measures, however, are needed to successfully contain and combat the virus in the United States.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States, by the authority vested in me by the Constitution and the laws of the United States of America, including sections 201 and 301 of the National Emergencies Act (50 U.S.C. 1601 *et seq.*) and consistent with section 1135 of the Social Security Act (SSA), as amended (42 U.S.C. 1320b–5), do hereby find and proclaim that the COVID–19 outbreak in the United States constitutes a national emergency, beginning March 1, 2020. Pursuant to this declaration, I direct as follows:

Section 1. *Emergency Authority*. The Secretary of HHS may exercise the authority under section 1135 of the SSA to temporarily waive or modify certain requirements of the Medicare, Medicaid, and State Children's Health Insurance programs and of the Health Insurance Portability and Accountability Act Privacy Rule throughout the duration of the public health emergency declared in response to the COVID–19 outbreak.

Sec. 2. *Certification and Notice*. In exercising this authority, the Secretary of HHS shall provide certification and advance written notice to the Congress as required by section 1135(d) of the SSA (42 U.S.C. 1320b–5(d)).

Sec. 3. *General Provisions*. (a) Nothing in this proclamation shall be construed to impair or otherwise affect:

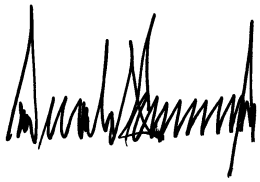
(i) the authority granted by law to an executive department or agency, or the head thereof; or

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

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

(c) This proclamation 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.

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



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Presidential Documents

Proclamation 9995 of March 13, 2020

National Poison Prevention Week, 2020

By the President of the United States of America

A Proclamation

Far too often, American families bear the burden of preventable tragedies caused by unintentional poisonings. Each day, more than 300 children are treated for poisonings in emergency rooms across the United States. These incidents frequently involve ordinary household items like cleaning products and medicines, including opioids, which are toxic but may be attractive to children because of their bright colors and sweet smells. The responsibility for ensuring that these dangerous products are out of sight and out of reach of our youth falls on all of us. During National Poison Prevention Week, we reaffirm our commitment to raising awareness of the realities of unintentional poisonings and overdoses in our country, and of the ways Americans can educate themselves to avoid accidental injury, overdose, or death in their homes and communities.

Every American has a role to play in preventing accidental poisonings and overdoses. Twice per year, my Administration hosts national drug ''Take Back Day'' events for Americans to help protect against the accidental ingestion, misuse, or abuse of prescription drugs by turning in expired or unneeded medications to be disposed of safely. Locking up medications after use and asking local pharmacies or police departments for ways to promptly dispose of expired, unwanted, or unused medications properly can also help prevent tragedies from occurring. In the event of an accidental poisoning, quick action could save a life, and expert help is always available through poison control centers. These centers are vital lifelines used by millions of Americans annually, and they serve the public, healthcare providers, public safety personnel, health departments, and law enforcement officials around the clock.

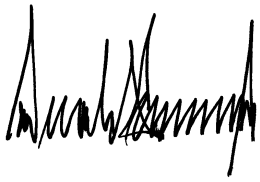
Each day, many American families suffer from the pain caused by an opioid overdose death. My Administration is committed to helping eradicate drug addiction from our society and to preventing drug overdoses, which are now the leading cause of accidental death in the United States. Over the last 3 years, the Department of Health and Human Services has awarded nearly $9 billion in grants to address the opioid crisis and improve access to prevention, treatment, and recovery services. As a part of my *Initiative to Stop Opioid Abuse*, I announced a plan to decrease the amount of opioid prescription fills by one-third within 3 years. And in October 2018, I signed into law the SUPPORT Act, the largest and most comprehensive piece of legislation to combat the opioid crisis, which expands access to drug-disposal programs and to evidence-based treatment for opioid use disorder. Thanks to our efforts, in 2018, overdose deaths fell nationwide for the first time in decades, and the amount of opioids prescribed nationally since 2017 decreased by 35 percent. Additionally, an increasing number of Americans are receiving life-saving medication-assisted treatment for drug addiction.

No American should perish as a result of unintended exposure to poisons or accidental overdoses. This week, we recommit to taking the critical precautions necessary to prevent the deadly realities of unintentional poisonings and drug overdoses, and we ask all Americans to do their part to raise awareness to help combat these issues.

To encourage Americans to learn more about the dangers of unintentional poisonings and to take appropriate preventative measures, on September 26, 1961, the Congress, by joint resolution (75 Stat. 681), authorized and requested the President to issue a proclamation designating the third week of March each year as ''National Poison Prevention Week.''

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, do hereby proclaim March 15, 2020, through March 21, 2020, to be National Poison Prevention Week. I call upon all Americans to observe this week by taking actions to safeguard their families from poisonous products, chemicals, medicines, and drugs found in their homes, and to raise awareness about these dangers in order to prevent accidental injuries and deaths.

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



[FR Doc. 2020–05795
Filed 3–17–20; 8:45 am]
Billing code 3295–F0–P

Presidential Documents

Proclamation 9996 of March 14, 2020

Suspension of Entry as Immigrants and Nonimmigrants of Certain Additional Persons Who Pose a Risk of Transmitting 2019 Novel Coronavirus

By the President of the United States of America

A Proclamation

On January 31, 2020, I issued Proclamation 9984 (Suspension of Entry as Immigrants and Nonimmigrants of Persons Who Pose a Risk of Transmitting 2019 Novel Coronavirus and Other Appropriate Measures To Address This Risk). I found that the potential for widespread transmission of a novel (new) coronavirus (which has since been renamed ''SARS–CoV–2'' and causes the disease COVID–19) (''SARS–CoV–2'' or ''the virus'') by infected individuals seeking to enter the United States threatens the security of our transportation system and infrastructure and the national security. Because the outbreak of the virus was at the time centered in the People's Republic of China, I suspended and limited the entry of all aliens who were physically present within the People's Republic of China, excluding the Special Administrative Regions of Hong Kong and Macau, during the 14-day period preceding their entry or attempted entry into the United States, subject to certain exceptions. On February 29, 2020, in recognition of the sustained person-to-person transmission of SARS–CoV–2 in the Islamic Republic of Iran, I issued Proclamation 9992 (Suspension of Entry as Immigrants and Nonimmigrants of Certain Additional Persons Who Pose a Risk of Transmitting 2019 Novel Coronavirus), suspending and limiting the entry of all aliens who were physically present within the Islamic Republic of Iran during the 14-day period preceding their entry or attempted entry into the United States, subject to certain exceptions. And, most recently, on March 11, 2020, I issued Proclamation 9993 (Suspension of Entry as Immigrants and Nonimmigrants of Certain Additional Persons Who Pose a Risk of Transmitting 2019 Novel Coronavirus), suspending and limiting the entry of all aliens who were physically present within the Schengen Area during the 14-day period preceding their entry or attempted entry into the United States, subject to certain exceptions.

The Centers for Disease Control and Prevention (CDC), a component of the Department of Health and Human Services, has determined that the virus presents a serious public health threat, and CDC continues to take steps to prevent its spread. But CDC, along with State and local health departments, has limited resources, and the public health system could be overwhelmed if sustained human-to-human transmission of the virus occurred in the United States on a large scale. Sustained human-to-human transmission has the potential to cause cascading public health, economic, national security, and societal consequences.

CDC has determined that the United Kingdom is experiencing widespread, ongoing person-to-person transmission of SARS–CoV–2. As of March 13, 2020, the World Health Organization reported that the United Kingdom had 594 cases of COVID–19, 5 times more cases than there were 7 days prior.

The Republic of Ireland has an open border with the United Kingdom in that persons can generally move freely between the Republic of Ireland and the United Kingdom—by land to and from Northern Ireland and by

ferry or aircraft to and from Wales, England, and Scotland. This general ability to travel freely between the United Kingdom and the Republic of Ireland poses the same challenges that the Schengen Area posed for suspending and limiting entry to the United States by travelers who had been physically present within any of the Schengen Area countries. CDC has also determined that the Republic of Ireland is experiencing ongoing sustained person-to-person transmission of SARS–CoV–2. As of March 13, 2020, the World Health Organization reported that the Republic of Ireland had 70 cases of COVID–19, 5 times more cases than there were 7 days prior.

The United States Government is unable to effectively evaluate and monitor all of the travelers continuing to arrive from the United Kingdom and the Republic of Ireland. The potential for undetected transmission of the virus by infected individuals seeking to enter the United States from the United Kingdom and the Republic of Ireland threatens the security of our transportation system and infrastructure and the national security. Given the importance of protecting persons within the United States from the threat of this harmful communicable disease, I have determined that it is in the interests of the United States to take action to restrict and suspend the entry into the United States, as immigrants or nonimmigrants, of all aliens who were physically present within the United Kingdom, excluding overseas territories outside of Europe, or the Republic of Ireland during the 14-day period preceding their entry or attempted entry into the United States. The free flow of commerce between the United States and the United Kingdom and the Republic of Ireland remains an economic priority for the United States, and I remain committed to facilitating trade between our nations.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States, by the authority vested in me by the Constitution and the laws of the United States of America, including sections 212(f) and 215(a) of the Immigration and Nationality Act, 8 U.S.C. 1182(f) and 1185(a), and section 301 of title 3, United States Code, hereby find that the unrestricted entry into the United States of persons described in section 1 of this proclamation would, except as provided for in section 2 of this proclamation, be detrimental to the interests of the United States, and that their entry should be subject to certain restrictions, limitations, and exceptions. I therefore hereby proclaim the following:

Section 1. *Suspension and Limitation on Entry*. The entry into the United States, as immigrants or nonimmigrants, of all aliens who were physically present within the United Kingdom, excluding overseas territories outside of Europe, or the Republic of Ireland during the 14-day period preceding their entry or attempted entry into the United States is hereby suspended and limited subject to section 2 of this proclamation.

Sec. 2. *Scope of Suspension and Limitation on Entry*.

(a) Section 1 of this proclamation shall not apply to:

(i) any lawful permanent resident of the United States;

(ii) any alien who is the spouse of a U.S. citizen or lawful permanent resident;

(iii) any alien who is the parent or legal guardian of a U.S. citizen or lawful permanent resident, provided that the U.S. citizen or lawful permanent resident is unmarried and under the age of 21;

(iv) any alien who is the sibling of a U.S. citizen or lawful permanent resident, provided that both are unmarried and under the age of 21;

(v) any alien who is the child, foster child, or ward of a U.S. citizen or lawful permanent resident, or who is a prospective adoptee seeking to enter the United States pursuant to the IR–4 or IH–4 visa classifications;

(vi) any alien traveling at the invitation of the United States Government for a purpose related to containment or mitigation of the virus;

(vii) any alien traveling as a nonimmigrant pursuant to a C–1, D, or C–1/D nonimmigrant visa as a crewmember or any alien otherwise traveling to the United States as air or sea crew;

(viii) any alien

(A) seeking entry into or transiting the United States pursuant to one of the following visas: A–1, A–2, C–2, C–3 (as a foreign government official or immediate family member of an official), E–1 (as an employee of TECRO or TECO or the employee's immediate family members), G–1, G–2, G–3, G–4, NATO–1 through NATO–4, or NATO–6 (or seeking to enter as a nonimmigrant in one of those NATO categories); or

(B) whose travel falls within the scope of section 11 of the United Nations Headquarters Agreement;

(ix) any alien whose entry would not pose a significant risk of introducing, transmitting, or spreading the virus, as determined by the Secretary of Health and Human Services, through the CDC Director or his designee;

(x) any alien whose entry would further important United States law enforcement objectives, as determined by the Secretary of State, the Secretary of Homeland Security, or their respective designees, based on a recommendation of the Attorney General or his designee;

(xi) any alien whose entry would be in the national interest, as determined by the Secretary of State, the Secretary of Homeland Security, or their designees; or

(xii) members of the U.S. Armed Forces and spouses and children of members of the U.S. Armed Forces.

(b) Nothing in this proclamation shall be construed to affect any individual's eligibility for asylum, withholding of removal, or protection under the regulations issued pursuant to the legislation implementing the Convention Against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, consistent with the laws and regulations of the United States.

Sec. 3. *Implementation and Enforcement*. (a) The Secretary of State shall implement this proclamation as it applies to visas pursuant to such procedures as the Secretary of State, in consultation with the Secretary of Homeland Security, may establish. The Secretary of Homeland Security shall implement this proclamation as it applies to the entry of aliens pursuant to such procedures as the Secretary of Homeland Security, in consultation with the Secretary of State, may establish.

(b) Consistent with applicable law, the Secretary of State, the Secretary of Transportation, and the Secretary of Homeland Security shall ensure that any alien subject to this proclamation does not board an aircraft traveling to the United States.

(c) The Secretary of Homeland Security may establish standards and procedures to ensure the application of this proclamation at and between all United States ports of entry.

(d) An alien who circumvents the application of this proclamation through fraud, willful misrepresentation of a material fact, or illegal entry shall be a priority for removal by the Department of Homeland Security.

Sec. 4. *Termination*. This proclamation shall remain in effect until terminated by the President. The Secretary of Health and Human Services shall recommend that the President continue, modify, or terminate this proclamation as described in section 5 of Proclamation 9984, as amended.

Sec. 5. *Effective Date*. This proclamation is effective at 11:59 p.m. eastern daylight time on March 16, 2020. This proclamation does not apply to persons aboard a flight scheduled to arrive in the United States that departed prior to 11:59 p.m. eastern daylight time on March 16, 2020.

Sec. 6. *Severability*. It is the policy of the United States to enforce this proclamation to the maximum extent possible to advance the national security, public safety, and foreign policy interests of the United States. Accordingly:

(a) if any provision of this proclamation, or the application of any provision to any person or circumstance, is held to be invalid, the remainder of this proclamation and the application of its provisions to any other persons or circumstances shall not be affected thereby; and

(b) if any provision of this proclamation, or the application of any provision to any person or circumstance, is held to be invalid because of the lack of certain procedural requirements, the relevant executive branch officials shall implement those procedural requirements to conform with existing law and with any applicable court orders.

Sec. 7. *General Provisions*. (a) Nothing in this proclamation shall be construed to impair or otherwise affect:

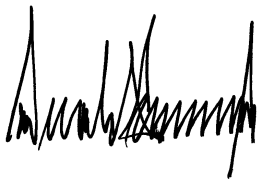
(i) the authority granted by law to an executive department or agency, or the head thereof; or

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

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

(c) This proclamation 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.

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



[FR Doc. 2020–05797
Filed 3–17–20; 8:45 am]
Billing code 3295–F0–P

Presidential Documents

Proclamation 9997 of March 14, 2020

National Day of Prayer for All Americans Affected by the Coronavirus Pandemic and for Our National Response Efforts

By the President of the United States of America

A Proclamation

In our times of greatest need, Americans have always turned to prayer to help guide us through trials and periods of uncertainty. As we continue to face the unique challenges posed by the coronavirus pandemic, millions of Americans are unable to gather in their churches, temples, synagogues, mosques, and other houses of worship. But in this time we must not cease asking God for added wisdom, comfort, and strength, and we must especially pray for those who have suffered harm or who have lost loved ones. I ask you to join me in a day of prayer for all people who have been affected by the coronavirus pandemic and to pray for God's healing hand to be placed on the people of our Nation.

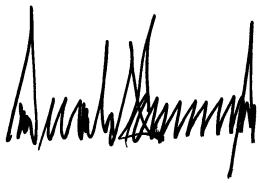
As your President, I ask you to pray for the health and well-being of your fellow Americans and to remember that no problem is too big for God to handle. We should all take to heart the holy words found in 1 Peter 5:7: ''Casting all your care upon him, for he careth for you.'' Let us pray that all those affected by the virus will feel the presence of our Lord's protection and love during this time. With God's help, we will overcome this threat.

On Friday, I declared a national emergency and took other bold actions to help deploy the full power of the Federal Government to assist with efforts to combat the coronavirus pandemic. I now encourage all Americans to pray for those on the front lines of the response, especially our Nation's outstanding medical professionals and public health officials who are working tirelessly to protect all of us from the coronavirus and treat patients who are infected; all of our courageous first responders, National Guard, and dedicated individuals who are working to ensure the health and safety of our communities; and our Federal, State, and local leaders. We are confident that He will provide them with the wisdom they need to make difficult decisions and take decisive actions to protect Americans all across the country. As we come to our Father in prayer, we remember the words found in Psalm 91: ''He is my refuge and my fortress: my God; in him will I trust.''

As we unite in prayer, we are reminded that there is no burden too heavy for God to lift or for this country to bear with His help. Luke 1:37 promises that ''For with God nothing shall be impossible,'' and those words are just as true today as they have ever been. As one Nation under God, we are greater than the hardships we face, and through prayer and acts of compassion and love, we will rise to this challenge and emerge stronger and more united than ever before. May God bless each of you, and may God bless the United States of America.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, do hereby proclaim March 15, 2020, as a National Day of Prayer for All Americans Affected by the Coronavirus Pandemic and for our National Response Efforts. I urge Americans of all faiths and religious traditions and backgrounds to offer prayers for all those affected, including people who have suffered harm or lost loved ones.

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



[FR Doc. 2020–05798
Filed 3–17–20; 8:45 am]
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Rules and Regulations

Federal Register

Vol. 85, No. 53

Wednesday, March 18, 2020

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.

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 34, 36, and 39

[NRC–2019–0031]

RIN 3150–AK29

Individual Monitoring Devices

AGENCY: Nuclear Regulatory Commission.

ACTION: Direct final rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is amending its regulations to authorize the use of modern individual monitoring devices in industrial radiographic, irradiator, and well logging operations. These amendments will align personnel dosimetry requirements in these areas with the requirements for all other NRC licensees. This direct final rule addresses an issue raised in a petition for rulemaking and will affect NRC and Agreement State licensees. The NRC also is issuing supplemental guidance for use and comment with this direct final rule.

DATES: This direct final rule and supplemental guidance are effective June 16, 2020. If adverse comments on the direct final rule are received by April 17, 2020 the direct final rule will be withdrawn. If the direct final rule is withdrawn, the supplemental guidance also is withdrawn; timely notice of the withdrawal will be published in the **Federal Register**. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date. If the direct final rule is withdrawn, comments will be addressed in a subsequent final rule. Comments received on this direct final rule and supplemental guidance will also be considered as comments on the companion proposed rule published in the Proposed Rules section of this issue of the **Federal Register**.

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

- *Federal Rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2019–0031. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Email comments to: Rulemaking.Comments@nrc.gov.* If you do not receive an automatic email reply confirming receipt, then contact us at 301–415–1677.
- *Fax comments to:* Secretary, U.S. Nuclear Regulatory Commission at 301–415–1101.
- *Mail comments to:* Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Rulemakings and Adjudications Staff.
- *Hand deliver comments to:* 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. (Eastern Time) Federal workdays; telephone: 301–415–1677.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Anthony McMurtray, telephone: 301–415–2746; email: *Anthony.McMurtray@nrc.gov;* or Edward Lohr, telephone: 301–415–0253; email: *Edward.Lohr@nrc.gov.* Both are staff of the Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

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I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2019–0031 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2019–0031.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2019–0031 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Rulemaking Procedure

Because the NRC considers this action to be non-controversial, the NRC is using the direct final rule procedure for this rule. The amendment to the rule will become effective on June 16, 2020. However, if the NRC receives significant adverse comments on this direct final rule by April 17, 2020, then the NRC will publish a document that withdraws this direct final rule, as well as the associated supplemental guidance. In such a case, the NRC will treat comments on this direct final rule as comments on the companion proposed rule published in the Proposed Rules section of this issue of the **Federal Register**. Absent significant modifications to the proposed revisions requiring republication, the NRC will not initiate a second comment period on this action.

A significant adverse comment is a comment where the commenter explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. A comment is adverse and significant if:

(1) The comment opposes the rule and provides a reason sufficient to require a substantive response in a notice-and-comment process. For example, a substantive response is required when:

(a) The comment causes the NRC to reevaluate (or reconsider) its position or conduct additional analysis;

(b) The comment raises an issue serious enough to warrant a substantive response to clarify or complete the record; or

(c) The comment raises a relevant issue that was not previously addressed or considered by the NRC.

(2) The comment proposes a change or an addition to the rule, and it is apparent that the rule would be ineffective or unacceptable without incorporation of the change or addition.

(3) The comment causes the NRC to make a change (other than editorial) to the rule.

For detailed instructions on filing comments, please see the **ADDRESSES** section of this document.

III. Background

The regulations in part 34 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations''; 10 CFR part 36, ''Licenses and Radiation Safety Requirements for Irradiators''; and 10 CFR part 39, ''Licenses and Radiation Safety Requirements for Well Logging,'' require the use of personnel dosimetry that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor. These regulations restrict the types of personnel dosimeters that can be used and prohibit the use of dosimetry technologies that do not require processing by an accredited NVLAP facility.

On July 14, 2016, the NRC received a petition for rulemaking (PRM) from the American Society for Nondestructive Testing and the Nondestructive Testing Management Association (the petitioners) (ADAMS Accession No. ML16228A045). The petition was docketed by the NRC on August 12, 2016, and assigned Docket No. PRM–34–7. The NRC published a notice of docketing of PRM–34–7 in the **Federal Register** (81 FR 78732) on November 9, 2016. The petitioners requested that the NRC amend its regulations and associated guidance to authorize the use of improved individual monitoring devices for industrial radiographic personnel. Specifically, the petitioners requested that the NRC amend its regulations to authorize the use of digital output personnel dosimeters to satisfy the personnel dosimetry requirements in § 34.47(a).

Personnel dosimetry is a specific type of dosimetry that is used to track an individual worker's dose. The petitioners interchangeably used the terms ''improved individual monitoring devices,'' ''electronic personnel monitoring dosimeters,'' ''electronic dosimeters,'' and ''digital personnel dosimeters'' to describe digital output personnel dosimetry. In this direct final rule, the NRC uses the term ''digital output personnel dosimetry'' in place of these terms. A digital output personnel dosimeter is a specific type of personnel dosimetry that currently cannot be used to meet the requirements in 10 CFR parts 34, 36, and 39 to demonstrate compliance with the occupational dose limits in § 20.1201.

On February 11, 2019, the NRC published a document in the **Federal Register** (84 FR 3116) informing the public that it would consider PRM–34–7 in the rulemaking process. In the **Federal Register** document, the NRC accepted the petitioners' request that the NRC amend its regulations to authorize the use of digital output personnel dosimeters for industrial radiographic personnel and expanded the scope of the rulemaking to include the use of digital output personnel dosimeters in irradiator and well logging operations.

IV. Discussion

The NRC's requirements related to the safe use of sealed sources of byproduct material in industrial radiography are codified in 10 CFR part 34. The regulation in § 34.47(a) states that during radiographic operations, radiographers and radiographer's assistants must wear ''a direct reading dosimeter, an operating alarm ratemeter, and a personnel dosimeter that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor.''

Although ''processing'' is not defined in the regulations, the NRC uses it with a specific meaning related to personnel dosimetry. The NRC interprets processing to mean a process, separate from and independent of the design of the dosimeter, that is required to extract dose information from the dosimeter after exposure to radiation. Processing is necessary with film, thermoluminescent dosimetry (TLD), and optically stimulated luminescence (OSL) dosimetry to obtain the dose information. With film, TLD, and OSL dosimetry, the quality of the processing is dependent on the competence of the processor and not on the dosimeter design, whereas quality is built into the design of dosimeters that do not require processing. An in-depth discussion on this topic can be found in the January 14, 2005, **Federal Register** document (70 FR 2577) denying a petition for rulemaking (PRM–20–25).

Film, TLD, and OSL dosimeters are examples of devices that require processing by qualified technicians using separate equipment to obtain data that is used to compute the dose measurement. Therefore, these types of dosimeters must be processed by an accredited NVLAP facility to ensure the quality of the processing. The NVLAP does not certify or accredit dosimetry devices themselves; it only certifies or accredits device processing. Accreditation by the NVLAP provides a level of assurance of quality of the measurement (*i.e.,* accuracy, precision, and reliability) for processors.

Some recently designed personnel dosimeters do not require the type of processing envisioned in the text of § 34.47(a)—that is, data extraction through a process independent of the dosimeter. For example, some personnel dosimeters can provide instantaneous dose readings using internet-enabled computers, smartphones, and tablets. Data is extracted from the detector and then digitally transferred from the dosimeter for computation. The design of the personnel dosimeter, rather than

the training and qualifications of the processing technician, ensures accurate dose information from the dosimeter after exposure to radiation.

Current regulations in § 34.47(a) and similar provisions in 10 CFR parts 36 and 39 require use of personnel dosimeters that require processing. This direct final rule eliminates these requirements for personnel dosimeters that require processing. The requirements in 10 CFR part 20 will continue to provide standards for the use of all personnel dosimeters.

The NRC considered recent peer-reviewed literature and NRC documents on the performance of digital output personnel dosimeters that were authorized by Agreement State and NRC licensees. The NRC determined that digital output personnel dosimetry has been used successfully by NRC licensees in other operational settings, by some Agreement State licensees in all areas—including industrial radiography, and internationally in multiple applications. The NRC did not find any evidence of generic performance problems with digital output personnel dosimetry in other operating settings, nor did the NRC identify any adverse trends that would preclude the use of this dosimetry by all NRC licensees.

In addition, the NRC evaluated the technical specifications of currently available digital output personnel dosimetry and determined that they met or exceeded performance standards, operability criteria (*e.g.,* temperature, humidity), dose ranges, and quality control expectations for use in industrial radiographic, irradiator, and well logging operations. The NRC did not identify issues that would preclude the use of digital output personnel dosimetry in industrial radiographic, irradiator, or well logging operations.

Therefore, the NRC determined that there is no technical basis for continuing to limit the types of personnel dosimeters used in industrial radiography, irradiator, and well logging operations to only those that are processed and evaluated by an accredited NVLAP processor. The levels and types of radiation fields encountered in these operations are also encountered in other industries where digital output personnel dosimeters already are allowed. The NRC determined that mandating the use of a particular type of personnel dosimetry will not prevent or reduce the dose received or result in more accurate, precise, or reliable measurements.

In addition, having access to digital output personnel dosimeters is especially beneficial to industrial radiography licensees. Under § 34.47(d), certain circumstances require workers to cease work immediately until their radiation dose has been determined. This can involve three or more days of wait time while the personnel dosimeter is sent off-site for processing and evaluation, which could cost the licensee revenue and lost time. Workers using digital output personnel dosimeters do not need to send their dosimeters to a processor and can have their radiation dose determined locally so that the issue can be resolved quickly.

Consistent with the agency's focus on implementing risk-informed, performance-based regulations and transforming its regulatory approaches, the NRC is amending the requirements for licensees under 10 CFR parts 34, 36, and 39 to enable the use of any personnel dosimeters. Removing the requirement to use personnel dosimeters that are processed and evaluated by an accredited NVLAP facility will allow the use of digital output personnel dosimeters (which do not require processing) and ensure all NRC licensees are held to the same standards for personnel dosimetry. Also, because the current regulations are based on the use of film, TLD, and OSL dosimeters (all of which require processing by an accredited NVLAP processor), conforming and clarifying changes related to exchange intervals, monitoring, and recordkeeping are being made to 10 CFR parts 34, 36, and 39 to address personnel dosimeters that do not require processing. These amendments will allow greater consistency with the Agreement States' programs.

On May 11, 2018, the NRC issued an Enforcement Guidance Memorandum (EGM–18–001) that provides guidance for dispositioning potential violations of NRC requirements for personnel dosimetry during NRC-licensed activities under 10 CFR parts 34, 36, and 39 (ADAMS Accession No. ML18068A623). In the EGM, the NRC stated that industrial radiographic, irradiator, and well logging licensees who use digital output personnel dosimetry for personnel monitoring (*i.e.,* dosimetry used for the dose of record) would not be subject to enforcement action for some potential violations of NRC requirements associated with the use of these dosimeters provided that specified conditions are met. The NRC considered the specific conditions specified in EGM–18–001 during the development of this direct final rule. The EGM will expire when this direct final rule becomes effective.

V. Guidance Documents

The NRC is issuing supplemental guidance in conjunction with this direct final rule. Guidance on 10 CFR parts 34, 36, and 39 is provided in NUREG–1556, ''Consolidated Guidance About Materials Licenses,'' in the volumes for industrial radiography (Volume 2), irradiators (Volume 6), and well logging (Volume 14). This supplemental guidance is intended for use by applicants, licensees, Agreement States, and the NRC staff when personnel dosimeters that do not require processing are being used. It includes guidance to applicants for the completion and submission of materials license applications to the NRC and model procedures that an applicant or licensee may consider when developing or changing its radiation safety program.

The supplemental guidance documents (ADAMS package Accession No. ML19360A184) are in a markup format to NRC's existing guidance and reflect the provisions in the direct final rule. On the effective date of the direct final rule, licensees that elect to use personnel dosimeters that do not require processing may use the supplemental guidance to comply with the provisions in the direct final rule.

Comments on the supplemental guidance may be submitted as directed in Section I, ''Obtaining Information and Submitting Comments,'' of this document. The NRC will incorporate this supplemental guidance into the next comprehensive revision of NUREG–1556.

VI. Section-by-Section Analysis

The following paragraphs describe the specific changes made in this direct final rule.

Section 34.47 Personnel Monitoring

In § 34.47, this direct final rule revises paragraph (a) by removing the requirement to use a personnel dosimeter that is processed and evaluated by an accredited NVLAP processer, revises paragraph (a)(3) to make conforming changes, and removes paragraph (a)(4).

Paragraph (d) is revised to include the requirement to begin evaluating an individual's personnel dosimeter within 24 hours for personnel dosimeters that do not require processing, if the conditions in the paragraph are met.

Paragraph (f) is revised to state that all dosimetry results received by a licensee are to be retained in accordance with § 34.83.

Section 34.83 Records of Personnel Monitoring Procedures

In § 34.83, this direct final rule revises paragraph (c) by removing the phrase ''received from the accredited NVLAP processor.''

Section 36.55 Personnel Monitoring

In § 36.55, this direct final rule revises paragraph (a) by removing the requirement to use a personnel dosimeter that is processed and evaluated by an accredited NVLAP processer and clarifying that all personnel dosimeters must be capable of detecting high energy photons in the normal and accident dose ranges. The reference to § 20.1501(c) is removed because it does not apply to all personnel dosimetry. Conforming changes are made to clarify that personnel dosimeters that require processing must be replaced at appropriate intervals, that all personnel dosimeters must be evaluated promptly after replacement and at least quarterly, and an individual's radiation dose must be determined at periods not to exceed three months.

Section 39.65 Personnel Monitoring

In § 39.65, this direct final rule revises paragraph (a) by removing the requirement to use a personnel dosimeter that is processed and evaluated by an accredited NVLAP processer. Conforming changes are made to clarify that personnel dosimeters that require processing must be replaced at appropriate intervals, that all personnel dosimeters must be evaluated promptly after replacement and at least quarterly, and an individual's radiation dose must be determined at periods not to exceed three months.

VII. Regulatory Analysis

The NRC has prepared a regulatory analysis (ADAMS Accession No. ML19283B555) to support this direct final rule. The analysis examines the costs and benefits of the alternatives considered by the NRC.

VIII. Regulatory Flexibility Certification

Under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the NRC certifies that this direct final rule will not, if issued, have a significant economic impact on a substantial number of small entities. This direct final rule affects a number of ''small entities'' as defined by the Regulatory Flexibility Act or the size standards established by the NRC (§ 2.810). However, as indicated in the regulatory analysis, these amendments do not have a significant economic impact on the affected small entities.

IX. Backfitting and Issue Finality

The revisions to 10 CFR parts 34, 36, and 39 would not constitute backfitting as these parts do not have a backfitting provision. In addition, the revisions would not impose any additional requirements. Personnel dosimeters that are not processed would be authorized for voluntary use by licensees, but not required.

X. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111–274) requires Federal agencies to write documents in a clear, concise, and well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, ''Plain Language in Government Writing,'' published June 10, 1998 (63 FR 31885).

XI. National Environmental Policy Act

The NRC has determined that this direct final rule is the type of action described in § 51.22(c)(2). Therefore, neither an environmental impact statement nor environmental assessment has been prepared for this direct final rule.

XII. Paperwork Reduction Act

This direct final rule does not contain any new or amended collections of information subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Existing collections of information were approved by the Office of Management and Budget, approval numbers 3150–0007, 3150–0130, and 3150–0158.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

XIII. Congressional Review Act

This direct final rule is a rule as defined in the Congressional Review Act (5 U.S.C. 801–808). However, the Office of Management and Budget has not found it to be a major rule as defined in the Congressional Review Act.

XIV. Compatibility of Agreement State Regulations

Under the ''Agreement State Program Policy Statement'' approved by the Commission on October 2, 2017 and published in the **Federal Register** on October 18, 2017 (82 FR 48535), the NRC program elements (including regulations) are placed into Compatibility Categories A, B, C, D, NRC, or Adequacy Category Health and Safety (H&S). Compatibility Category A are those program elements that are basic radiation protection standards and scientific terms and definitions that are necessary to understand radiation protection concepts. An Agreement State should adopt Category A program elements in an essentially identical manner in order to provide uniformity in the regulation of agreement material on a nationwide basis. Compatibility Category B are those program elements that apply to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. Compatibility Category C are those program elements that do not meet the criteria of Category A or B, but the essential objectives of which an Agreement State should adopt to avoid conflict, duplication, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a national basis. An Agreement State should adopt the essential objectives of the Category C program elements. Compatibility Category D are those program elements that do not meet any of the criteria of Category A, B, or C, and thus, do not need to be adopted by Agreement States for purposes of compatibility. Compatibility Category NRC are those program elements that address areas of regulation that cannot be relinquished to the Agreement States under the Atomic Energy Act of 1954, as amended, or provisions of title 10 of the *Code of Federal Regulations*. These program elements should not be adopted by the Agreement States. Compatibility Category H&S are program elements that are required because of a particular health and safety role in the regulation of agreement material within the State and should be adopted in a manner that embodies the essential objectives of the NRC program.

This direct final rule is a matter of compatibility between the NRC and the Agreement States, thereby providing consistency among Agreement State and the NRC requirements. The compatibility categories are designated in the following table:

COMPATIBILITY TABLE

Section	Change	Subject	Compatibility	
			Existing	New
Part 34:				
34.47(a)	Amend	Personnel monitoring	C	C
34.47(a)(3)	Amend	Personnel monitoring	C	C
34.47(d)	Amend	Personnel monitoring	C	C
34.47(f)	Amend	Personnel monitoring	C	C
34.83(c)	Amend	Records of personnel monitoring	C	C
Part 36:				
36.55(a)	Amend	Personnel monitoring	H&S	H&S
Part 39:				
39.65(a)	Amend	Personnel monitoring devices	C	C

XV. Voluntary Consensus Statement

The National Technology Transfer and Advancement Act of 1995, Public Law 104–113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this direct final rule, the NRC will revise parts 34, 36, and 39 by removing the requirement to use a personnel dosimeter that is processed and evaluated by an accredited NVLAP processer. This action does not constitute the establishment of a standard that contains generally applicable requirements.

List of Subjects

10 CFR Part 34

Criminal penalties, Manpower training programs, Occupational safety and health, Packaging and containers, Penalties, Radiation protection, Radiography, Reporting and recordkeeping requirements, Scientific equipment, Security measures, X-rays.

10 CFR Part 36

Byproduct material, Criminal penalties, Nuclear energy, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment, Security measures.

10 CFR Part 39

Byproduct material, Criminal penalties, Labeling, Nuclear energy, Nuclear material, Occupational safety and health, Oil and gas exploration—well logging, Penalties, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment, Security measures, Source material, Special nuclear material.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; the Nuclear Waste Policy Act of 1982, as amended; and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR parts 34, 36, and 39:

PART 34—LICENSES FOR INDUSTRIAL RADIOGRAPHY AND RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

■ 1. The authority citation for part 34 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 81, 161, 181, 182, 183, 223, 234, 274 (42 U.S.C. 2111, 2201, 2231, 2232, 2233, 2273, 2282, 2021); Energy Reorganization Act of 1974, secs. 201, 206 (42 U.S.C. 5841, 5846); 44 U.S.C. 3504 note.

■ 2. In § 34.47:

■ a. In paragraph (a) introductory text, remove the phrase ''that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor'';

■ b. Revise paragraph (a)(3);

■ c. Remove paragraph (a)(4); and

■ d. Revise paragraphs (d) and (f).

The revisions read as follows:

§ 34.47 Personnel monitoring.

(a) * * *

(3) Film badges must be replaced at least monthly and all other personnel dosimeters that require replacement must be replaced at least quarterly. All personnel dosimeters must be evaluated at least quarterly or promptly after replacement, whichever is more frequent.

* * * * *

(d) If an individual's pocket chamber is found to be off-scale, or if his or her electronic personal dosimeter reads greater than 2 millisieverts (200 millirems), and the possibility of radiation exposure cannot be ruled out as the cause, the individual's personnel dosimeter that requires processing must be sent for processing and evaluation within 24 hours. For personnel dosimeters that do not require processing, evaluation of the dosimeter must be started within 24 hours. In addition, the individual may not resume work associated with licensed material use until a determination of the individual's radiation dose has been made. This determination must be made by the RSO or the RSO's designee. The results of this determination must be included in the records maintained in accordance with § 34.83.

* * * * *

(f) Dosimetry results must be retained in accordance with § 34.83.

* * * * *

§ 34.83 [Amended]

■ 3. In § 34.83(c), remove the phrase ''received from the accredited NVLAP processor''.

PART 36—LICENSES AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

■ 4. The authority citation for part 36 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 81, 161, 181, 182, 183, 223, 234, 274 (42 U.S.C. 2111, 2112, 2201, 2231, 2233, 2273, 2282, 2021); Energy Reorganization Act of 1974, secs. 201, 206 (42 U.S.C. 5841, 5846); 44 U.S.C. 3504 note.

■ 5. In § 36.55, revise paragraph (a) to read as follows:

§ 36.55 Personnel monitoring.

(a) Irradiator operators shall wear a personnel dosimeter while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The personnel dosimeter must be capable of detecting high energy photons in the normal and accident dose ranges. Each personnel dosimeter must be assigned to and worn by only one individual. Film badges must be replaced at least monthly and all other personnel dosimeters that require replacement must be replaced at least quarterly. All personnel dosimeters

must be evaluated at least quarterly or promptly after replacement, whichever is more frequent.

* * * * *

PART 39—LICENSES AND RADIATION SAFETY REQUIREMENTS FOR WELL LOGGING

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

Authority: Atomic Energy Act of 1954, secs. 53, 57, 62, 63, 65, 69, 81, 161, 181, 182, 183, 223, 234 (42 U.S.C. 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2112, 2201, 2232, 2233, 2273, 2282); Energy Reorganization Act of 1974, secs. 201, 206 (42 U.S.C. 5841, 5846); 44 U.S.C. 3504 note.

■ 7. In § 39.65, revise paragraph (a) to read as follows:

§ 39.65 Personnel monitoring.

(a) The licensee may not permit an individual to act as a logging supervisor or logging assistant unless that person wears a personnel dosimeter at all times during the handling of licensed radioactive materials. Each personnel dosimeter must be assigned to and worn by only one individual. Film badges must be replaced at least monthly and all other personnel dosimeters that require replacement must be replaced at least quarterly. All personnel dosimeters must be evaluated at least quarterly or promptly after replacement, whichever is more frequent.

* * * * *

Dated at Rockville, Maryland, this 3rd day of March, 2020.

For the Nuclear Regulatory Commission.

Margaret M. Doane,

Executive Director for Operations.

[FR Doc. 2020–05295 Filed 3–17–20; 8:45 am]

BILLING CODE 7590–01–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

14 CFR Part 1241

[Document Number NASA–20–028: Docket Number—NASA–2020–0001]

RIN 2700–AE51

To Research, Evaluate, Assess, and Treat (TREAT) Astronauts

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Interim final rule; request for comments.

SUMMARY: With this interim final rule, the National Aeronautics and Space Administration (NASA) is amending its regulations to add a new part that will implement the provisions of the TREAT Astronauts Act. The new regulations will provide for the medical monitoring and diagnosis of conditions that are potentially spaceflight-associated and treatment of conditions that are spaceflight-associated for former U.S. Government astronauts and payload specialists.

DATES:

Effective: March 18, 2020.

Comments due: Send comments on or before May 18, 2020.

ADDRESSES: You may send comments, identified by docket number NASA–2019–0004 and/or RIN number 2700–AE51, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for sending comments.
- *Email: HQ-TREATAstronautsAct@nasa.gov.* Include docket number NASA–2019–0004 and/or RIN number 2700–AE51 in the subject line of the message.
- *Mail:* NASA Headquarters, Mail Code 2M21, ATTN: Gwyn E. Smith, 300 E St. SW, Washington, DC 20546–0001.

Instructions: All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Gwyn E. Smith, Policy Manager, Office of the Chief Health and Medical Officer, 1–833–996–1685, *HQ-TREATAstronautsAct@nasa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

NASA currently has a voluntary medical monitoring program, Lifetime Surveillance of Astronaut Health (LSAH) program, for all U.S. Government astronauts and payload specialists at the NASA Johnson Space Center (JSC). Once they leave the astronaut corps, former U.S. Government astronauts and payload specialists rely on workers' compensation and other U.S. Government programs to provide diagnosis and treatment for spaceflight-associated conditions. There is no formal mechanism for NASA to receive diagnosis and treatment data on such conditions.

As of November 2019, there are approximately 250 living former U.S. Government astronauts and payload specialists. The Agency currently affords occupationally related medical monitoring services through the LSAH program to former U.S. Government astronauts and payload specialists at the JSC with a 60–70 percent participation rate.

On March 21, 2017, the President signed into law the National Aeronautics and Space Administration Transition Authorization Act of 2017, Public Law 115–10 (2017). Title IV, Subtitle D, the ''To Research, Evaluate, Assess, and Treat Astronauts Act'' (hereafter ''TREAT Astronauts Act'' or ''Act'') is codified at Section 20149 of Title 51 of the U.S. Code.

The TREAT Astronauts Act provides NASA the authority to expand the voluntary monitoring program by developing a more comprehensive occupational surveillance program that will enable earlier detection and diagnosis of medical conditions ''potentially associated'' with spaceflight and treatment of medical conditions associated with spaceflight. NASA currently uses data from the LSAH program to tailor clinical care for individual astronauts, as well as to inform the human systems risks, current spaceflight operations, and future vehicle standards. The comprehensive occupational surveillance program will provide NASA with more comprehensive data that will ultimately contribute to an improved understanding of the long-term impact of spaceflight. This enhanced program is expected to increase the former U.S. Government astronaut and payload specialist participation rate in the occupational surveillance program to over 80 percent.

Human spaceflight poses significant challenges and is full of substantial risk. NASA and its astronauts acknowledge and accept the risks of spaceflight are beyond those of ordinary daily living. Participation in long duration missions or multiple shorter duration missions, increases health risks such as, vision impairment, bone demineralization, and behavioral health issues. In addition, exposure to high levels of radiation and microgravity can result in acute and long-term health consequences that can increase the risk of cancer and tissue degeneration and have potential effects on the musculoskeletal system, central nervous system, cardiovascular system, immune function, and vision.

NASA has also seen an increase in health issues former U.S. Government astronauts and payload specialists face, many years after their NASA service. One of the vital tools NASA needs to prepare for future long-duration and exploration missions is more data on the health effects humans face in

spaceflight. Data collected under the TREAT Astronauts Act will allow NASA to examine health trends in astronauts over the course of their lifetime to understand better the physical, behavioral, microbiological, and molecular reaction of the human body. These data will also contribute to the overall knowledge of the Agency and serve to identify spaceflight risks to human health and develop mitigation strategies as NASA moves ahead to long-duration and exploration missions. Given the fact that there are so few astronauts and such limited data, increased participation to get more data is critical. NASA is learning daily of the untoward effects of human spaceflight on the human body. In order to prepare for the Moon in 2024, NASA needs to understand these effects so appropriate mitigation measures can be taken now.

This program will inform future generations by providing health data showing the effects of spaceflight activities on active and former U.S. Government astronauts and payload specialists and thereby ensuring that their legacy and NASA's mission continues. This data will become increasingly valuable to improving our understanding of many diseases humans face on Earth.

II. Section-by-Section Analysis

Section 1241.10 Covered Medical Care

This section establishes key tenets of the program as defined in the TREAT Astronauts Act unless specifically stated otherwise. NASA will provide monitoring and diagnosis for conditions potentially associated with spaceflight and treatment for conditions associated with spaceflight. For clarity and ease of reading, we are using ''spaceflight-associated condition'' as defined in 14 CFR 1241.15 versus ''condition associated with spaceflight'' as used in the TREAT Astronauts Act. Monitoring, diagnosis, and treatment will be provided by a local health care provider if it is unadvisable for the former U.S. Government astronaut or payload specialist to travel to the JSC. A provision has been added to also allow for monitoring, diagnosis, and treatment at a local health care provider if it is advantageous to the Government. For example, if additional tests are needed after the individual has returned home from JSC, they could be done locally if it is more cost effective. NASA will provide medical monitoring, diagnosis, and treatment without a cost sharing obligation imposed on the former U.S. Government astronaut or payload specialist. This means NASA will pay, as a secondary payer, for any medical costs associated with the monitoring and diagnosis of a condition that is potentially associated with spaceflight and will pay, as the secondary payer, for any medical costs associated with the treatment of a condition that is associated with spaceflight. This includes deductibles, coinsurance, copayments, and similar charges, but excludes insurance premiums. Lastly, the law limits NASA's authority to pay for medical treatment to the role of secondary payer. The type of primary coverage available to former U.S. Government astronauts and payload specialists will depend on their status at the time of their active astronaut career and any current health plan, Federal benefits program, or other workers' compensation coverage that may apply. For former U.S. Government astronauts and payload specialists who believe they have a condition related to their spaceflight, they must first seek treatment from the Department of Defense Military Health System, the Department of Labor Office of Workers' Compensation Programs Division of Federal Employees' Compensation, or through their private health insurance, where applicable. The JSC Flight Medicine Clinic will assist the former U.S. Government astronauts and payload specialists with these processes as well as filing a claim with NASA.

Section 1241.15 Definitions

This section defines terms used in the TREAT Astronauts Act and this rule. We define:

—''Conditional payments'' as described in the TREAT Astronauts Act. This helps ensure the U.S. Government astronauts and payload specialists get prompt monitoring, diagnosis, and treatment for potential spaceflight-associated conditions, prior to primary payer formal claim submission and adjudication, as appropriate.

—''Cost sharing'' as described in the TREAT Astronauts Act prescribes that former U.S. Government astronauts and payload specialists participating in the program will receive monitoring, diagnosis, and treatment without cost sharing obligation. This means that medical monitoring, diagnosis, or treatment authorized under this Act shall be provided without any deductible, copayment, or other cost sharing obligation.

—''Monitoring, diagnosis, and treatment'' as consistent with current use in the medical community. Diagnosis and treatment are provided, consistent with the accepted standard of care. However, due to the unique nature of spaceflight, monitoring is based on a NASA astronaut spaceflight exposure clinical assessment. For example, as part of routine monitoring, NASA provides bone density scanning for young healthy males. This testing is beyond the accepted standard of care.

—''Eligible individual'' to include both former U.S. Government astronauts and former payload specialists who have flown in space, while specifically excluding others who are not included in these groups. U.S. Government astronaut is defined in the TREAT Astronauts Act as the meaning given the term ''Government astronaut'' in 51 U.S.C. 50902, except it does not include an individual who is an international partner astronaut. The term ''Government astronaut'' is defined in 51 U.S.C. 50902.

For clarification, the following are specifically excluded:

(1) Astronauts of other United States Government agencies—only astronauts who participate in NASA programs are eligible under the TREAT Astronauts Act, so if Department of Defense or Department of Labor, for example, had astronauts, they would not be covered under the TREAT Astronauts Act;

(2) Employees of commercial spaceflight companies who were never employed by NASA nor a member of the Uniformed Services assigned to NASA—commercial spaceflight astronauts, *i.e.,* astronauts who flew for commercial spaceflight companies, even if they participated in a mission to a NASA vehicle, say the International Space Station, are not eligible under the TREAT Astronauts Act;

(3) International partner astronauts—a term used specifically for NASA's partners in the International Space Station, excluding Russia, are specifically excluded in the TREAT Astronauts Act;

(4) Employees of foreign governments—astronauts who have flown to space with NASA but are not U.S. Government astronauts are not eligible; and

(5) Private individuals or tourists who have flown in space—private individuals and tourists who have flown to space with NASA, but are not U.S. Government astronauts are not eligible; and

(6) Former astronauts, including members of the Uniformed Services, and former payload specialists who have not flown in space—The definition of U.S. Government astronauts includes only those individuals who have flown into space, and therefore, those who have not flown to space are not eligible under the TREAT Astronauts Act.

We use the term ''eligible individual'' in this rule instead of the compound term ''former U.S. Government astronaut and former payload specialists'' as used in the TREAT Astronauts Act to clarify specifically who may participate in this program.

—''Program'' to mean the medical monitoring, diagnosis, and treatment authorized by the TREAT Astronauts Act to enhance the readability of the rule.

—''Primary Payer'' as it is commonly used within the medical community. Primary payer means the entity that pays first, up to the limits of its coverage.

—''Secondary Payer'' to mean the entity that pays after all primary payers have paid, up to the limits of their coverage. This means NASA will pay, in toto, as the secondary payer for any monitoring and diagnosis for potentially spaceflight-associated conditions and for any treatment for spaceflight-associated conditions. This includes any out-of-pocket cost-sharing expenses not covered by the primary payers.

—''Spaceflight-Associated Condition'' to mean the same as the TREAT Astronauts Act ''condition associated with spaceflight.'' This change in terminology enhances readability of the rule.

—''TREAT Astronauts Act Board (TAAB)'' as the internal NASA board that makes recommendations to the NASA Administrator or designee. The internal NASA charter for this board will detail the functions, membership, and operations. The decision-making process is detailed in 14 CFR 1241.6.

Section 1241.20 Eligibility

This section addresses eligibility of the former U.S. Government astronauts and payload specialists. There are currently approximately 250 former U.S. Government astronauts and payload specialists who may participate in this program. Eligible individuals must also meet other requirements defined herein to receive monitoring, diagnosis, and treatment under this program. Participation is strictly voluntary, that is, NASA cannot require former U.S. Government astronaut and payload specialists to participate.

Section 1241.25 Basic Program

This section describes the basic components of the program offered to former U.S. Government astronauts and payload specialists. In addition to providing monitoring, diagnosis, and treatment, NASA, as part of the no cost sharing obligation, will also cover travel expenses incurred. NASA currently covers travel expenses for its occupational surveillance program and will extend this no cost sharing across the program. Monitoring of potentially spaceflight-associated conditions is nominally provided at the JSC Flight Medicine Clinic. When necessary, due to the health of the former U.S. Government astronaut or payload specialist, monitoring may be provided locally, so as not to burden the eligible individual with travel. In addition, NASA may also opt to use a provider local to the eligible individual, if it is otherwise advantageous to the Government. This allows NASA to reduce costs as much as possible. Diagnosis and treatment is handled on a case-by-case basis, with the location of the provider dependent on the medical appropriateness of the facility, patient, preferences, cost effectiveness, and other pertinent factors. Each case is different and this allows NASA to provide the best possible care for each eligible individual. Eligible individuals who agree to participate in this program must agree that NASA is entitled to copies of any medical records associated with the monitoring, diagnosis, and treatment. They must further agree to submit all paperwork necessary for NASA to obtain copies of these records. And finally, they must agree that NASA may use and disclose this data within the limits of the law.

NASA will provide monitoring and diagnosis of eligible individuals for conditions potentially associated with spaceflight and treatment for spaceflight-associated conditions. NASA provides a lifetime occupation surveillance program, which includes a standard set of monitoring offered yearly to former U.S. Government astronauts and payload specialists. In addition to this yearly offering, additional monitoring is provided, as necessary, based on each eligible individual's medical needs. A provision has been added specifically for NASA to also request autopsies, as part of monitoring, be performed as they may contribute substantially to the knowledge of spaceflight physiology or pathology.

As mentioned previously, NASA is not authorized to provide monitoring and diagnosis for conditions not potentially associated with spaceflight or treatment for conditions not spaceflight-associated. Should a condition be diagnosed that is not related to spaceflight, the individual will be referred to their primary care physician.

Section 1241.30 Program Participation and Claims Submission

This section details the steps an eligible individual must take, with assistance from the JSC Flight Medicine Clinic, to participate in this program. Former U.S. Government astronauts and payload specialists already receive an annual invitation from NASA to participate in NASA's occupational surveillance program. No claim is required to participate in NASA's occupational surveillance program. This current program has a 60–70 percent participation rate. Eligible individuals must first seek primary coverage before submitting a claim to NASA, as NASA is a secondary payer. The type of primary coverage available to former U.S. Government astronauts and payload specialists will depend on their status at the time of their active astronaut career and any current health plan, Federal benefits program, or other workers' compensation coverage that may apply. For former U.S. Government astronauts and payload specialists who believe they have a condition related to their spaceflight, they must first seek treatment from the Department of Defense Military Health System, the Department of Labor Office of Workers' Compensation Programs Division of Federal Employees' Compensation, or through their private health insurance, where applicable. If the eligible individual is enrolled, or eligible to be enrolled in the U.S. Department of Veterans Affairs (VA) health care system and chooses to obtain care and services through VA, the individual will receive health care benefits in accordance with chapter 17 of title 38, United States Code, as implemented by the Secretary of Veterans Affairs. Moreover, as to the costs of VA care and services, there will be no ''coordination of benefits,'' as this term is generally understood in the health care industry, between VA and NASA. That is, VA would pay the full cost of the care. Under the TREAT Astronauts program, the eligible individual may seek reimbursement from NASA for any out-of-pocket copayment(s) he or she paid to VA for care of a condition that NASA determines is associated with spaceflight; and finally, VA has no special treatment authority (or copayment exemption) for former U.S. Government astronauts and payload specialists seeking treatment for conditions associated with spaceflight. As to compensation for disability related to service in the Armed Forces, an eligible individual who has Veteran status is free to file a claim for disability compensation with the Veterans

Benefits Administration, pursuant to 38 CFR part 3. The JSC Flight Medicine Clinic will assist the former U.S. Government astronauts and payload specialists with these processes as well as filing a claim with NASA.

This section also details the specific information required to submit a claim to NASA and identifies a website where additional information is available. The NASA Flight Medical Clinic will assist eligible individuals with claims submission, but is not authorized to prepare the claim on behalf of the eligible individual.

Section 1241.35 Claims Review and Decision

This section explains the review and decision-making process for claims submitted to NASA by eligible individuals. The TREAT Astronauts Act Board (TAAB) is an internal NASA board of physicians who will review claims submitted to NASA. The TAAB will consider all information, including information about other exposures, provided for a case and consult with other experts and specialists as appropriate. The TAAB will provide a recommendation to the Administrator or designee who will make the final decision on approval or denial of the claim. The eligible individual will be notified of the decision promptly and, should the claim be denied, be afforded the opportunity to submit additional information for reconsideration of the claim. There is no limit to the number of times an eligible individual can submit new information through a reconsideration request.

Section 1241.40 Payment of Approved Claims

This section details the payment process for approved claims. NASA payments are applied secondarily to other U.S. Government entities or primary payers and may include the remaining out-of-pocket costs from primary payer coverage. Travel expenses are paid consistent with the Federal Travel Regulations and may include expenses for an assistant should the eligible individual need travel assistance. Conditional payments are also allowed to ensure the eligible individual gets the care needed promptly. NASA may attempt to recover these costs from the primary payer or the eligible individual if the claim is subsequently denied.

Section 1241.45 Collaboration With Other Agencies

This section simply states that NASA will collaborate with other agencies as necessary to acquire medical records as allowable by law. As a condition of participating in the program, eligible individuals will have consented to allowing NASA to collect this information.

Section 1241.50 Records, Confidentially, Privacy and Data Use

This section states that NASA will adhere to all required privacy regulations and policies and will enter into data sharing agreements with other agencies as necessary to obtain required data.

III. Effect of Rulemaking

Title 14 of the Code of Federal Regulations, as revised by this interim final rulemaking, represents NASA's implementation of its legal authority on this subject. Other than future amendments to this regulation or governing statutes, no contrary guidance or procedures are authorized. All existing or subsequent NASA guidance must be read to conform with this rulemaking, if possible, or if not possible, such guidance is superseded by this rulemaking.

IV. Regulatory Analysis Section

Administrative Procedure Act (APA)

The Administrative Procedure Act requires notice of any proposed rule to be published in the **Federal Register** ''unless persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with the law,'' 5 U.S.C. 553(b). NASA has determined that through its extensive outreach efforts that actual notice has been provided to all interested parties—250 former astronauts and payload specialists, including several current Federal employees, and that this rule has no effect on the public beyond the 250 former astronauts. In drafting these regulations, NASA officials met with former U.S. Government astronauts and payload specialists, communicating and soliciting input from as many individuals as possible, through a variety of venues, including communications from the former NASA Administrator, professional meetings, the Potomac Institute for Policy Studies, the annual astronaut reunion, newsletters, online via the Life Sciences Data Archive and NASA TREAT Astronauts Act websites, as well as personal communications with former astronauts on how best to implement the program. These mechanisms have allowed us to notify the small group of interested individuals and enabled them opportunities to provide NASA with input regarding the development of this program. While an internet posting and a single meeting has been found insufficient to replace publication in the **Federal Register**, *see Utility Solid Waste Activities Grp.* v. *EPA,* 236 F.3d 749, 754 (D.C. Cir. 2001), NASA's efforts to provide actual notice was much more expansive and successful. *See Common Carrier Conference-Irregular Route* v. *United States,* 534 F.2d 981, 982 (D.C. Cir. 1976) (finding notice adequate because the affected parties were ''generally on notice'' through conduct of agency). Based on the forgoing, the agency has concluded that the individuals affected by this regulation have received actual notice and that publication in the **Federal Register** is not necessary. Nevertheless, for the avoidance of potential controversy and because of potential public interest, NASA has decided to publish these regulations as an interim final rule in the **Federal Register**.

In accordance with 5 U.S.C. 553, the Administrator of NASA has also concluded that there is good cause to publish this rule without prior opportunity for public comment. Good cause may be shown when the Agency finds that ''notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.'' *See* 5 U.S.C. 553(b)(B). Furthermore, in accordance with 5 U.S.C. 553, the Administrator of NASA has concluded there is good cause to publish this rule with an immediate effective date. An agency may dispense with the required 30 day effective date if ''as otherwise provided by the agency for good cause found and published with the rule.'' See 5 U.S.C. 553(d)(3).

As explained above, on March 21, 2017, the President signed into law the NASA Transition Act of 2017. The TREAT Astronauts Act, which is part of the NASA Transition Act of 2017, gives NASA the authority to provide former U.S. Government astronauts and payload specialists medical monitoring and diagnosis for conditions that are potentially spaceflight associated and treatment for conditions that are spaceflight associated.

As directed by Congress in section 443 of Public Law 115–10, NASA first entered into an arrangement with an independent external organization to undertake an independent estimate of the cost to the Administration and the Federal Government to implement and administer activities under the TREAT Astronauts Act. This cost estimate was submitted to both the House Science, Space and Technology Committee and the Senate Commerce, Science and Transportation Committee on March 14, 2018. NASA also, as directed by

Congress, carried out a study on any potential privacy or legal issues related to the possible sharing beyond the Federal Government of data acquired under the TREAT Astronauts Act. This was submitted to both the House Science, Space and Technology Committee and the Senate Commerce, Science and Transportation Committee on January 2, 2018. With the completion of these reports, NASA then began drafting these regulations.

In drafting these regulations, NASA officials met with former U.S. Government astronauts and payload specialists, as discussed more fully above. NASA also met with officials from the Department of Labor, Department of Veterans' Affairs, and the Defense Health Agency, critical partner agencies, who have an important stake in the outcome, on how best to collaborate and how to implement any required data sharing agreements.

Good Cause. To establish a good cause exception to the APA requirement to publish a proposed rule, an Agency must show that notice would be either impracticable, unnecessary, or contrary to the public interest. *See* 5 U.S.C. 553(b)(B). An agency is further required to establish good cause for publishing a substantive rule less than 30 days before its effective date. *See* 5 U.S.C. 553(d)(3). NASA believes that publication of a proposed rule is unnecessary and that there is good cause for the effective date of this rule to be less than 30 days after the date of publication.

Human space exploration poses significant challenges and is full of risk. With more recent long-duration space flight missions, NASA has seen the increased health risks that current U.S. Government astronauts face, such as vision impairment, bone demineralization, and exposure to radiation. NASA has also seen the increased health risks that former U.S. Government astronauts and payload specialists face, many years after their NASA service. Consequently, it is critical that NASA move forward with this rule without delay to ensure claims that are associated with human spaceflight are fully covered.

One of the vital tools NASA needs to prepare for future long-duration and exploration missions is data on the health effects human face in spaceflight. NASA needs these data to better understand the physical, behavioral, microbiological, and reaction on the molecular level of the human body to an extended period of time in space. Former U.S. Government astronauts and payload specialists who voluntarily participate in this program will be consenting to providing their medical data to NASA. Given the fact that there are so few astronauts and such limited data, increased participation to get more data is critical. NASA is learning daily of the untoward effects of human spaceflight on the human body. In order to prepare for the Moon in 2024, NASA needs to understand these effects so that we can take appropriate mitigation measures now.

As discussed more fully above, it is critical for NASA to start treating former U.S. Government astronauts and payload specialists for medical conditions that we are now beginning to understand many years later may be the results of their prior space flight exposure. We have also learned more recently of the urgency of early diagnosis and treatment and that former astronauts may present symptoms differently than the general population. Due to the small population of astronauts, it is imperative that we increase our collection of data immediately so that we can utilize it to mitigate the risks of spaceflight to future and current astronauts and take care of those former astronauts with conditions associated with spaceflight. Since Astronaut Scott Kelly's 2015–2016 record year in space, nineteen astronauts have participated in longer space duration flights of up to one year, and NASA's goal is to return to the Moon by 2024. By increasing the population of former astronauts who are being monitored, NASA will be able to better understand the effects of space flight and institute ameliorative measures.

The unnecessary prong of the good cause inquiry is ''confined to those situations in which the administrative rule is a routine determination, insignificant in nature and impact, and inconsequential to the industry and the public. *See Mack Trucks, Inc.,* v. *EPA,* 682 F.3d 87, 94 (D.C. Cir. 2012). This new rule applies only to a very limited and easily discernable group of beneficiaries—approximately 250 former U.S. Government astronauts and payload specialists. It does not affect any other member of the public in any significant way and, therefore, advanced notice is unnecessary.[1]

The Agency has also established good cause for dispensing with the 30-day delay in the effective date in accordance with 5 U.S.C. 553(d)(3). Unlike the notice and comment requirements, which are designed to ensure public participation in rulemaking, the 30-day waiting period is intended to give affected parties time to adjust their behavior before the final rule takes effect. Given the limited number of parties affected by the new rule, the facts that participation is voluntary and those impacted would like to be treated immediately, the urgency of the matter, and the discussion above, good cause has been shown.

For these reasons, the Agency will publish this rule without prior opportunity for public comment and with an immediate effective date. Thus, the Administrator issues this rule as an interim final rule with request for comments.

Executive Order 12866—Regulatory Planning and Review and Executive Order 13563—Improving Regulation and Regulatory Review

Executive Orders (E.O.) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. This rule is a significant regulatory action and has been reviewed by the Office of Management and Budget in accordance with E.O. 12866.

Executive Order 13771—Reducing Regulations and Controlling Regulatory Costs

This rule is not expected to be an E.O. 13771 regulatory action because this rule is expected to be related to agency organization, management, or personnel.

Regulatory Flexibility Act

It has been certified that this rule is not subject to the Regulatory Flexibility Act (5 U.S.C. 601) because it would not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act

This rule contains information collection requirement subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). These requirements are found under Office of Management and Budget control number 2700–0171, NASA TREAT Astronauts Act.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the

[1] As discussed above, the Agency believes that actual notice has been provided to former astronauts rendering the publication requirement of the APA unnecessary.

private sector, of $100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments.

List of Subjects in 14 CFR Part 1241

Health, Medical, Astronaut.

■ For reasons set forth in the preamble, NASA adds part 1241 to 14 CFR chapter V to read as follows:

PART 1241—TO RESEARCH, EVALUATE, ASSESS, AND TREAT (TREAT) ASTRONAUTS

Sec.
1241.05 Purpose and scope
1241.10 Covered medical care
1241.15 Definitions
1241.20 Eligibility
1241.25 Basic program
1241.30 Program participation and claims submission
1241.35 Claims review and decisions
1241.40 Payment of approved claims
1241.45 Collaboration with other agencies
1241.50 Records, confidentially, privacy, and data use

Authority: 51 U.S.C. 20149.

§ 1241.05 Purpose and scope.

(a) This part establishes a program and sets out the eligibility requirements and procedures to effectuate section 443 of the ''To Research, Evaluate, Assess, and Treat Astronauts Act of 2017.''

(b) The purpose of this program is to provide medical monitoring and diagnosis of former U.S. Government astronauts and payload specialists for conditions the Administrator considers potentially associated with spaceflight and to provide treatment of former U.S. Government astronauts and payload specialists for conditions the Administrator considers associated with spaceflight.

§ 1241.10 Covered medical care.

(a) Subject to the limitations in paragraph (b) of this section, an eligible individual, as defined in § 1241.15, is eligible for:

(1) Monitoring and diagnosis for potentially spaceflight-associated conditions; and

(2) Treatment for spaceflight-associated conditions.

(b) Medical monitoring, diagnosis, and treatment authorized and described in paragraph (a) of this section will not be provided for any condition that is found by the NASA Administrator or designee to have resulted from a cause other than the eligible individual's participation in spaceflight-related activities. Should a condition be diagnosed that is not related to spaceflight, the individual will be referred to their primary care physician.

(c) Medical monitoring, diagnosis, and treatment authorized and described in paragraph (a) of this section may be provided by a local health care provider if the NASA Administrator or designee determines it is unadvisable for the eligible individual to travel to the NASA Johnson Space Center (JSC) due to the individual's condition or if it is otherwise advantageous to the Government.

(d) Medical monitoring, diagnosis, and treatment authorized and described in paragraph (a) of this section will be provided without a cost sharing obligation imposed on the eligible individual.

(e) NASA is a secondary payer.

§ 1241.15 Definitions.

Conditional Payment means a NASA payment to a medical provider or eligible individual to pay for the cost of medical monitoring, diagnosis, and treatment. Such conditional payments may be made prior to a formal determination that a psychological or medical condition is spaceflight-associated if payment has not been made or cannot reasonably be expected to be made promptly by the primary payer.

Cost Sharing means a multiparty arrangement under which costs of a program are shared by the involved parties, according to an agreed upon formula. For this program, there is no cost sharing obligation by the eligible individual. The eligible individual is responsible for insurance premiums.

Diagnosis means the identification of a medical or psychological condition consistent with the exercise of professional clinical judgment and accepted standard of care by licensed health professionals.

Eligible Individual means a former United States Government astronaut, including a member of the Uniformed Services, or a former payload specialist who has flown in space, as defined in the TREAT Astronauts Act. The following individuals are specifically excluded from eligible individuals:

(1) Astronauts of other United States Government agencies;

(2) Employees of commercial spaceflight companies who were never employed by NASA nor a member of the Uniformed Services assigned to NASA;

(3) International partner astronauts;

(4) Employees of foreign governments;

(5) Private individuals or tourists who have flown in space; and

(6) Former astronauts, including members of the Uniformed Services, and former payload specialists who have not flown in space.

JSC means Johnson Space Center.

Monitoring means the NASA astronaut spaceflight exposure clinical assessment of medical and psychological health status by licensed health professionals.

Payload Specialist means an individual other than a NASA astronaut (commander, pilot, and mission specialist) whose presence was required onboard the space shuttle vehicle to perform specialized functions with respect to operation of one or more payloads or other essential mission activities.

Primary Payer means the entity, U.S. Government agency or private health insurer, which is responsible to make payment to the eligible individual first, up to the limits of its coverage or authority.

Program means the medical monitoring, diagnosis, and treatment authorized by the TREAT Astronauts Act.

Secondary Payer means the entity that pays after all primary payers have paid, up to the limits of their coverage. Secondary payments, as described in the TREAT Astronauts Act, are payments or reimbursement for the medical monitoring, diagnosis, or treatment secondary to any obligation of the U.S. Government or any third party under any other provision of law or contractual agreement to pay for or provide such medical monitoring, diagnosis, or treatment.

Spaceflight-Associated Condition means a medical or psychological condition that the NASA Administrator or designee designated by the NASA Administrator determines is at least as likely as not to have resulted from participation in spaceflight-related activities.

Treatment means the accepted standard of clinical care for a medical or psychological condition by licensed health professionals.

TREAT Astronauts Act means section 443 of the ''To Research, Evaluate, Assess, and Treat Astronauts Act of 2017.''

TREAT Astronauts Act Board or TAAB means the internal NASA review board that provides recommendations to the NASA Administrator or designee as to whether or not a medical claim initiated by an eligible individual meets the standards for spaceflight association for medical monitoring, diagnosis, and treatment under the TREAT Astronauts Act.

U.S. Government Agency means ''agency'' as defined in 5 U.S.C. 551.

§ 1241.20 Eligibility.

(a) This section sets forth those persons who, by the provisions of the

TREAT Astronauts Act, are eligible to participate in this program. A determination by the Administrator or designee that a person is eligible does not automatically entitle such a person to medical monitoring, diagnosis, and treatment under the TREAT Astronauts Act.

(b) Only eligible individuals defined in § 1241.15 are entitled to medical monitoring, diagnosis, and treatment under this part.

(c) Participation in this program is strictly voluntary. NASA may not require an eligible individual to participate in this program.

§ 1241.25 Basic program.

(a) *General*—(1) *Scope.* Subject to all applicable definitions, conditions, limitations, or exclusions specified in this part, NASA will provide medical monitoring and diagnosis of potentially spaceflight-associated conditions and treatment of a spaceflight-associated conditions, as well as any associated travel expenses for the eligible individual's lifetime.

(2) *Location of medical monitoring, diagnosis, and treatment.* (i) Medical monitoring will be provided for eligible individuals at the JSC.

(ii) When travel is inadvisable due to the health of the eligible individual or when otherwise advantageous to the Government, monitoring may be provided at a location other than the JSC.

(iii) Diagnosis and treatment will be provided for eligible individuals at locations determined by the medical appropriateness of the facility, patient preferences, cost effectiveness, and other pertinent factors.

(3) *Right to information.* As a condition precedent to participation in this program, NASA is entitled to receive copies of medical records from any physician, hospital or other person, health insurance company, institution, or entity (including a local, state, or U.S. Government agency) providing medical monitoring, diagnosis, and treatment to the eligible individual for which claims or requests for approval for medical monitoring, diagnosis, and treatment are submitted to NASA. As part of this condition precedent, NASA may require eligible individuals to complete such medical releases needed to facilitate obtaining such information as legally required by state and Federal law.

(b) *Monitoring and Diagnosis.* NASA will provide monitoring and diagnosis for eligible individuals for conditions potentially associated with spaceflight.

(1) Standardized monitoring will be offered routinely at the JSC.

(2) Individualized monitoring will be provided, as necessary.

(3) NASA may pay for and obtain autopsies of eligible individuals, who previously consented in writing or with consent of the next of kin, when such autopsy would contribute substantially to the knowledge of spaceflight physiology or pathology. NASA will coordinate with the Armed Forces Medical Examiner System for such autopsies.

(c) *Treatment.* NASA will provide or arrange for the treatment of spaceflight-associated conditions.

(1) Treatment will be secondary to any services provided by primary payers.

(2) Should urgency dictate, NASA may provide for conditional payments for treatment.

(d) *Exclusions and limitations.* In addition to any definitions, requirements, conditions, or limitations enumerated and described in other sections of this part, the following are specifically excluded:

(1) Medical monitoring or diagnosis of an eligible individual for any medical or psychological condition that is not potentially associated with human spaceflight; and

(2) Treatment of an eligible individual for any medical or psychological condition that is not associated with human spaceflight.

§ 1241.30 Program participation and claims submission.

(a) *General program participation.* An eligible individual, or their authorized representative, who seek to participate in this program must provide the information set forth in paragraph (e)(2) of this section to NASA. The JSC Flight Medicine Clinic will assist eligible individuals through these processes.

(b) *NASA's occupationally related medical monitoring services.* (1) Eligible individuals will receive an annual invitation from NASA to participate in NASA's occupational surveillance program;

(2) [Reserved]

(c) *Primary payer coverage of diagnosis and treatment services.* (1) *Former Civil Servants.* Eligible individuals who were civil servant employees during their active astronaut or payload specialist career who believe they have sustained a spaceflight-associated condition and are seeking coverage for medical treatment under this part must submit a notice of injury and claim for compensation through their agency to the Department of Labor, Office of the Workers' Compensation Programs Division of Federal Employees' Compensation (DFEC) consistent with 5 U.S.C. Chapter 81 and 20 CFR part 10 before making a claim under the TREAT Astronauts Act.

(2) *Members of the Uniformed Services.* Eligible individuals who were members of the Uniformed Services during their active astronaut or payload specialist career, or who are otherwise determined to be eligible by their Uniformed Service and who believe they have sustained a spaceflight-associated condition must contact their Service to determine eligibility for health and dental care and/or coverage through the Military Health System of the Department of Defense, consistent with 10 U.S.C. Chapter 55 and 32 CFR part 199 before making a claim under the TREAT Astronauts Act.

(3) *Former Civil Servants who were also Members of the Uniformed Services.* Eligible individuals whose active astronaut career spanned both military and civil service will first submit a notice to the Department of Labor who will work with the Department of Defense.

(4) *Eligible individuals with claims denied or partially covered.* If the eligible individual's claim under paragraphs (c)(1), (2), or (3) of this section is either denied or covered only in part by the primary payer, the eligible individual can apply for medical monitoring, diagnosis, and treatment under this program.

(d) *Diagnosis and Treatment or Other Benefits-Veterans.* An eligible individual who is enrolled, or eligible to be enrolled, in the U.S. Department of Veterans Affairs (VA) health care system may opt instead to seek his or her care and services through the VA. Under the TREAT Astronauts program, the eligible individual may seek reimbursement from NASA for any out-of-pocket copayment(s) he or she paid to VA for care of a condition that NASA determines is associated with spaceflight. The individual may also apply for disability compensation with the Department of Veterans Affairs, Veterans Benefits Administration, pursuant to 38 CFR part 3.

(e) *Submitting claims for medical monitoring, diagnosis, and treatment under this program*—(1) *Claim required.* (i) No medical diagnosis and treatment may be extended under the TREAT Astronauts Act without submission of a complete claim form to the JSC Flight Medicine Clinic.

(ii) NASA will provide specific forms appropriate for making a claim for medical monitoring, diagnosis, and treatment. Claim forms may be obtained from the JSC Flight Medicine Clinic. Contact information can be found at: *https://www.nasa.gov/hhp/treat-act.*

(2) *Information required.* Each claim for medical monitoring, diagnosis, and treatment under this program will be in writing and include, at a minimum:

(i) Statement of eligibility describing the employment and spaceflight history that justifies medical monitoring, diagnosis, and treatment under this program;

(ii) History and diagnosis of medical or psychological condition;

(iii) Medical documentation in support of the claim. Healthcare providers must be licensed and permitted to practice under state law and not be on the Centers for Medicare & Medicaid Services (CMS) List of Excluded Individuals and Entities, found at: *https://healthdata.gov/dataset/list-excluded-individuals-and-entities;*

(iv) Documentation of the decisions and/or payments made by the primary payer (*i.e.,* other U.S. Government agencies and/or private health insurer) regarding the claim;

(v) Justification for determination that the psychological or medical condition is associated with spaceflight;

(vi) Expenses for which they are seeking reimbursement, to include documentation of all out-of-pocket costs; and

(vii) The signature of the eligible individual or their authorized representative.

(3) *Responsibility for perfecting claim.* It is the responsibility of the eligible individual, authorized representative, or the authorized provider acting on behalf of the eligible individual to perfect a claim for submission. NASA will assist eligible individuals with claims submission, but is not authorized to prepare a claim on behalf of the eligible individual.

§ 1241.35 Claims review and decisions.

(a) NASA will establish the TREAT Astronauts Act Board (TAAB) to review claims for medical monitoring, diagnosis, and treatment under this program. This review is independent of any review conducted by primary payers.

(b) The TAAB will review each claim submitted by the eligible individual, in consultation with specialists, as appropriate. A typical case will be reviewed within 30 calendar days, but cases that are more complex may take additional time.

(c) The TAAB will make a recommendation to the Administrator or designee for each claim stating whether the condition is determined to be spaceflight associated.

(d) For those eligible individuals who have had other exposures in addition to those experienced during their career as active U.S. Government astronauts or payload specialists, the TAAB will consider that history when making its recommendation.

(e) The NASA Administrator or designee will review each claim and associated TAAB recommendation to determine whether the claim should be approved or denied. A typical case can be reviewed within 30 calendar days, but cases that are more complex may take additional time.

(f) The decision will be provided to the eligible individual within seven calendar days of the final decision by the NASA Administrator or designee. Decisions not in favor of the eligible individual will include information on how to request reconsideration.

(g) An eligible individual or their authorized representative may request reconsideration of the decision at any time if new information is obtained that enhances the claim. Reconsideration requests can be made to the JSC Flight Medicine Clinic.

(h) Requests for reconsideration are reviewed by the TAAB and decisions made by the Administrator or designee, following the same process described in paragraphs (b) through (f) of this section.

§ 1241.40 Payment of approved claims.

(a) The NASA Administrator or designee is responsible for ensuring that medical monitoring, diagnosis, and treatment to eligible individuals under this program is paid only to the extent described in this part.

(b) Payment for medical monitoring, diagnosis, and treatment is applied secondarily to primary payers and may include the remaining out-of-pocket costs from primary payer coverage.

(c) NASA will pay necessary travel expenses related to this program consistent with the Federal Travel Regulations.

(d) NASA may provide conditional payments for medical monitoring, diagnosis, and treatment that is obligated to be paid by the U.S. Government or other primary payers prior to a final decision by NASA in accordance with § 1241.35. Such requests for conditional payments can be made to JSC Flight Medicine Clinic. Such payments are permitted when payment for such medical monitoring, diagnosis, and treatment has either not been made or will not be made promptly.

(1) NASA may seek to recover costs associated with conditional payments from the U.S. Government, private health insurance company, or other primary payer as allowable by law.

(2) If the claim is denied in accordance with § 1241.35, NASA may seek to recover such conditional payments from the eligible individual in accordance with 31 U.S.C. Chapter 37.

§ 1241.45 Collaboration with other agencies.

Copies of records generated from medical monitoring, diagnosis, and treatment collected by primary payer facilities and/or relevant health care providers will be acquired by NASA. NASA will collaborate with the Department of Defense Military Health System, Department of Veterans Affairs, and Department of Labor Office of Workers' Compensation and other entities for acquisition of copies of these medical records as allowed by law.

§ 1241.50 Records, confidentiality, privacy, and data use.

(a) Records on individuals created or obtained pursuant to this regulation that are subject to the Privacy Act of 1974, as amended, 5 U.S.C. 552a, will be maintained in accordance with the NASA's Privacy Act System of Records.

(b) NASA will, as necessary, enter into data sharing agreements with other agencies and/or entities to receive such data and/or seek signed medical releases from the eligible individuals, or their authorized representatives, in accordance with law.

(c) NASA's collection, use, and disclosure of this data will be in accordance with the Privacy Act of 1974, NASA's implementing regulations at 14 CFR part 1212, and NASA's privacy policies, where applicable.

Nanette Smith,

Team Lead, NASA Directives and Regulations.

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BILLING CODE 7510–13–P

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 30

RIN 3038–AE86

Foreign Futures and Options Transactions

AGENCY: Commodity Futures Trading Commission.

ACTION: Final rule.

SUMMARY: The Commodity Futures Trading Commission (Commission) is issuing a final rule that amends its regulations governing the offer and sale of foreign futures and options to customers located in the U.S. The amended regulation codifies the process

by which the Commission may terminate exemptive relief issued pursuant to its regulations.

DATES: The rule is effective March 18, 2020.

FOR FURTHER INFORMATION CONTACT: Joshua Sterling, Director, *jsterling@cftc.gov*; Frank Fisanich, Chief Counsel, *ffisanich@cftc.gov*; or Andrew Chapin, Associate Chief Counsel, *achapin@cftc.gov,* Division of Swap Dealer and Intermediary Oversight, Commodity Futures Trading Commission, 1155 21st Street NW, Washington, DC 20581, (202) 418–5000.

SUPPLEMENTARY INFORMATION:

I. Background

Part 30 of the Commission's regulations governs the offer and sale of futures and option contracts traded on or subject to the regulations of a foreign board of trade (foreign futures and options) to customers located in the U.S.[1] These regulations set forth requirements for foreign firms acting in the capacity of a futures commission merchant (FCM), introducing broker, commodity pool operator and commodity trading adviser with respect to the offer and sale of foreign futures and options to U.S. customers and are designed to ensure that such products offered and sold in the U.S. are subject to regulatory safeguards comparable to those applicable to transactions entered into on designated contract markets. Pursuant to § 30.10(a), persons located outside the U.S. and subject to a comparable regulatory structure in the jurisdiction in which they are located may seek an exemption from certain of the requirements under part 30 of the Commission's regulations based upon compliance with the regulatory requirements of the person's home jurisdiction.[2]

A petition for exemption pursuant to § 30.10(a) typically is filed on behalf of persons located and doing business outside the U.S. that seek access to U.S. customers by: (1) A governmental agency responsible for implementing and enforcing the foreign regulatory program; or (2) a self-regulatory organization (SRO) of which such persons are members. A petitioner who seeks an exemption pursuant to § 30.10(a) must set forth with particularity the comparable regulations applicable in the jurisdiction in which that person is located. The Commission may, in its discretion, grant such an exemption if it is demonstrated to the Commission's satisfaction that the exemption is not otherwise contrary to the public interest or to the purposes of the provision from which exemption is sought. Appendix A to part 30, Interpretative Statement With Respect to the Commission's Exemptive Authority Under § 30.10 of Its Rules (appendix A), generally sets forth the elements the Commission will evaluate in determining whether a particular regulatory program may be found to be comparable for purposes of exemptive relief pursuant to § 30.10,[3] and specifically states that in considering an exemption request, the Commission will take into account the extent to which United States persons or contracts regulated by the Commission are permitted to engage in futures-related activities or be offered in the country from which an exemption is sought.[4]

If the Commission determines that relief pursuant to § 30.10(a) is appropriate, the Commission issues an Order to the person that filed the petition for relief (typically the foreign regulator or SRO) that sets forth conditions governing such relief. After the relief is granted to the foreign regulator or SRO, persons under its regulatory oversight and located and doing business outside the U.S. may solicit or accept orders directly from U.S. customers for foreign futures or options transactions and, in the case of a person acting in the capacity of an FCM, accept customer money or other property, without registering under the CEA in the appropriate capacity.[5] The Commission reserves the right within each Order issued pursuant to § 30.10(a) to condition, modify, suspend, terminate, or otherwise restrict the exemptive relief granted, as appropriate, on its own motion.

II. The Proposal

The Commission published for public comment in the **Federal Register** on July 5, 2019 a notice of proposed rulemaking (the Proposal) proposing amendments to regulation § 30.10.[6] As noted above, § 30.10(a) sets forth the process by which any person adversely affected by any requirement set forth in part 30 may file a petition with the Commission seeking an exemption. While § 30.10(a) provides that the Commission may grant an exemption subject to any terms or conditions it may find appropriate, the regulation does not provide a specific course of action should the Commission determine that exemptive relief is no longer warranted. Accordingly, the Commission proposed to amend § 30.10 by adding a new paragraph (c) to codify the process by which the Commission may terminate exemptive relief issued pursuant to paragraph (a).

Specifically, the Proposal provided that the Commission may terminate exemptive relief, after appropriate notice and an opportunity to respond, under certain circumstances. First, the Commission could terminate the relief should it determine that there has been a material change or omission in the facts and circumstances pursuant to which relief was granted that demonstrate that the standards set forth in appendix A forming the basis for granting such relief are no longer met. Second, the Commission could terminate relief should it determine that the continued exemptive relief would be contrary to the public interest or inconsistent with the purposes of the regulation § 30.10 exemption. For example, in considering whether exemptive relief continues to be warranted, the Commission could take into account any material changes in the applicable regulatory regime, including a lack of comity relating to the execution or clearing of any commodity interest[7] subject to the Commission's exclusive jurisdiction.[8] Third, the Commission could terminate relief should it determine that information-sharing arrangements no longer adequately support exemptive relief.

The Proposal also provided any affected person with an appropriate opportunity to respond to any notice by the Commission issued pursuant to § 30.10(c)(1). The affected person is the foreign regulator, SRO, or other entity that filed the original petition for relief.[9] The Commission proposed that the timing for any opportunity to respond would take into account the exigency of circumstances. The Commission noted that it is able to suspend immediately the relief set forth in any Order issued pursuant to § 30.10(a) should exigent circumstances occur. Thus, the Proposal stated that the affected party would have a period of 30 business days, or

[1] 17 CFR part 30. The Commission promulgated part 30 of its regulations in 1987. *See* Foreign Futures and Foreign Options Transactions, 52 FR 28980 (Aug. 5, 1987). The Commission promulgated these regulations pursuant to Section 2(b)(2)(A) of the Commodity Exchange Act (CEA), 7 U.S.C. 6(b)(2)(A).

[2] 17 CFR 30.10(a).

[3] 52 FR 28990, 29001.

[4] 17 CFR part 30, appendix A.

[5] The term ''futures commission merchant'' is defined in § 1.3, 17 CFR 1.3.

[6] *See* Foreign Futures and Options Transactions, 84 FR 32105 (Jul. 5, 2019).

[7] The term ''commodity interest'' includes, among other things, any contract for the purchase or sale of a commodity for future delivery, or any swap as defined in the CEA. *See* 17 CFR 1.3.

[8] The Commission's exclusive jurisdiction is set forth in 7 U.S.C. 2(a).

[9] Paragraph (a) of the current regulation states that any person adversely affected by any requirement of this part may file a petition. 17 CFR 30.10(a).

such time as the Commission permits in writing to respond to the notification. This time period could be less than 30 business days depending on the exigency of the circumstances and other relevant considerations.

Should the Commission ultimately determine to terminate any exemptive relief, it proposed that the Commission would be required to notify the affected person in writing setting forth the particular reasons why relief is no longer warranted and issue an Order terminating exemptive relief to be published in the **Federal Register**. Proposed § 30.10(c)(2)–(4) provided further that any Order terminating exemptive relief would set forth an appropriate time frame for the orderly transfer or close out of any accounts held by U.S. customers impacted by such an Order. Finally, proposed § 30.10 (c)(5) provided that any person whose relief has been terminated may re-apply for exemptive relief 360 days after the issuance of the relevant Order by the Commission if the deficiency causing the revocation has been cured or relevant facts and circumstances have changed.

III. Comments

The Commission received three comment letters on the Proposal from the Intercontinental Exchange, Inc. (ICE); the Futures Industry Association (FIA); and the CME Group Inc. (CME Group).[10] Each of the commenters commended the long-standing success of the Commission's program for regulatory deference set forth in § 30.10 and generally supported the Proposal to provide greater transparency to the process by which the Commission may terminate exemptive relief.

Both CME Group and FIA urged the Commission to adhere to the standard set forth in appendix A regarding principles of regulatory comity. In particular, these commenters noted that the Commission, in consideration of any petition submitted pursuant to § 30.10(a), should take into account the extent to which U.S. persons or contracts regulated by the Commission are permitted to engage in futures-related activities or be offered in the country from which an exemption is sought. Both commenters recognized that complementary regulatory programs of mutual recognition across jurisdictional boundaries reduce artificial barriers to market access, encourage liquidity, promote price discovery, and mitigate market fragmentation. Otherwise, market intermediaries will be required to comply with more costly, overlapping regulation that fail to take into account the market structure and participants in local markets.

With respect to specific rule text, both ICE and FIA requested that the final regulation provide all market participants—and not simply the foreign regulator or SRO to which the Order was issued—with notice and opportunity to comment on any notification by the Commission of its intention to terminate exemptive relief. Both commenters noted that market intermediaries taking advantage of such relief would be better positioned to plan for, and potentially mitigate, any possible business and market disruptions resulting from the termination of relief with formal notice from the Commission.

IV. Final Rule

The Commission has considered the comments from ICE, FIA, and CME Group and is adopting § 30.10(c) as proposed, with two modifications. The Commission agrees with comments that market intermediaries taking advantage of such relief and other market participants impacted by the potential termination of relief may provide helpful insight to the Commission as it considers whether termination is appropriate. Accordingly, the Commission is adopting a change to proposed § 30.10(c)(2) to provide parties other than the affected person with notice of and opportunity to comment on any potential termination of relief.

Revised § 30.10(c)(2) will require the Commission to publish on its website any notice of an intention to terminate relief. The Commission expects that the notice would be published on the website at substantially the same time that it is sent to the affected person, subject to any logistical or similar considerations. In this manner, market intermediaries—and derivatively, their U.S. customers—will be prompted to communicate with the Commission regarding any issues relevant to the potential termination of relief, including those regarding the potential transfer of customer accounts and property. The Commission also is adopting a corresponding change to § 30.10(c)(3) to provide persons other than the affected party with the opportunity to respond to the notification in writing no later than 30 business days following the publication on the Commission's website of the notification, or at such time as the Commission permits in writing (which could be more or less than 30 business days, depending on the exigency of the circumstances and other relevant considerations).

V. Related Matters

A. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires that Federal agencies consider whether the rules that they issue will have a significant economic impact on a substantial number of small entities and, if so, to provide a regulatory flexibility analysis regarding the impact on those entities. Each Federal agency is required to conduct an initial and final regulatory flexibility analysis for each rule of general applicability for which the agency issues a general notice of proposed rulemaking.[11]

As noted in the Proposal, this rule would affect foreign members of foreign boards of trade who perform the functions of an FCM. While the RFA may not apply to foreign entities,[12] the Commission previously determined that FCMs should be excluded from the definition of small entities.[13] Accordingly, the Chairman, on behalf of the Commission, hereby certifies, pursuant to 5 U.S.C. 605(b), that the final regulations will not have a significant impact on a substantial number of small entities.

B. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA) imposes certain requirements on Federal agencies, including the Commission, in connection with their conducting or sponsoring any collection of information, as defined by the PRA. Under the PRA, 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 control number from the Office of Management and Budget (OMB). The final regulations adopted would result in a collection of information within the meaning of the PRA, as discussed below. Therefore, the Commission is submitting the Final Rules to OMB for approval.

As discussed in the Proposal, final § 30.10(c)(2) will result in a collection of information within the meaning of the PRA, as discussed below. This final rule contains a collection of information for

[10] The comment letters can be found at: *https://comments.cftc.gov/PublicComments/CommentList.aspx?id=3002*.

[11] *See* U.S.C. 601 *et seq.*

[12] *See* 13 CFR 121.105 (noting that a small business is a business entity organized for profit, with a place of business located in the U.S., and which operates primarily within the U.S., or which makes a significant contribution to the U.S. economy through payment of taxes or use of American products, materials or labor).

[13] *See, e.g.,* Policy Statement and Establishment of Definitions of ''Small Entities'' for purposes of the Regulatory Flexibility Act, 47 FR 18618, 18619 (Apr. 30, 1982).

which the Commission has not previously received control numbers from the Office of Management and Budget (OMB). As noted in the Proposal, the Commission has submitted to OMB an information collection request to obtain an OMB control number for the collection contained in this proposal in accordance with 44 U.S.C. 3507(d) and 5 CFR 1320.11.

Specifically, final § 30.10(c)(3) provides any party affected by the Commission's determination to terminate relief with the opportunity to respond to the notification in writing no later than 30 business days following the receipt of the notification, or at such time as the Commission permits in writing. The Commission estimates that, if adopted, it would receive one response to this collection resulting in eight burden hours annually.

In the Proposal, the Commission invited the public and other Federal agencies to comment on any aspect of the proposed information collection requirements discussed therein.[14] The Commission did not receive any such comments.

C. Cost-Benefit Considerations

1. Summary

Section 15(a) of the CEA [15] requires the Commission to consider the costs and benefits of its actions before promulgating a regulation under the CEA or issuing certain orders. The baseline for this consideration of costs and benefits is the current status, where the Commission has not codified the procedures by which the Commission may terminate exemptive relief issued pursuant to § 30.10(a). As noted in the Proposal, the Commission has not yet terminated such relief, so the Commission has not yet implemented a procedure for terminating such exemptions. Moreover, the Commission has limited relevant or useful quantitative data to assess the potential costs and benefits of the final regulation § 30.10(c). Accordingly, the Commission generally considered the costs and benefits of final regulation § 30.10(c) in qualitative terms. The Commission invited comment on its preliminary consideration of the costs and benefits associated with the proposed changes to § 30.10,[16] and received no such comments.

As a general matter, final § 30.10(c) will inform the public, affected persons and market participants of the basis on which the Commission may terminate exemptive relief pursuant to § 30.10(a) and establishing a process whereby an affected party would first be notified and given an opportunity to respond before the Commission would take any action. The affected party will benefit from the clear process set forth in the final regulation. The affected person will only incur costs in connection with the final regulation to the extent that the Commission identified a basis for terminating the exemption and notified the party of that basis. Similarly, market participants and other interested members of the public would incur costs in connection with responding to the posting of the notice on the Commission's website. Those costs would include reviewing and responding to the notification, which the Commission believes would vary depending on the circumstances, including the stated basis for termination. As stated above, the Commission believes that 30 days, or such additional or less time as the Commission may permit in writing due to any exigent circumstances, will be sufficient for the affected person and other interested parties to develop a response while allowing the Commission to take timely action to consider their interests.

The Commission requested comment on the potential costs and benefits of proposed § 30.10(c), including, where possible, quantitative data, and on any alternative proposals that might achieve the objectives of the proposed regulation, and the costs and benefits associated with any such alternatives.[17] The Commission did not receive any such comments.

2. Section 15(a) Factors

Section 15(a) specifies that the costs and benefits shall be evaluated in light of five broad areas of market and public concern: (1) Protection of market participants and the public; (2) efficiency, competitiveness, and financial integrity of the futures markets; (3) price discovery; (4) sound risk management practices; and (5) other public interest considerations.

The Commission is considering the costs and benefits of these rules in light of the specific provisions of Section 15(a) of the CEA:

a. *Protection of Market Participants and the Public.* Section 15(a)(2)(A) of the CEA requires the Commission to evaluate the costs and benefits of a proposed regulation in light of protection of market participants and the public. The final regulations will benefit affected persons, market participants and the public by setting forth a clear procedure for the Commission's termination of exemptive relief issued pursuant to § 30.10(a). The final regulations will provide affected persons, market participants and the public with a reasonable timeframe to communicate any concerns to the Commission and, if necessary, for the orderly transfer of any accounts held by U.S. customers impacted by an order terminating relief.

b. *Efficiency, Competitiveness, and Financial Integrity of Markets.* Section 15(a)(2)(B) of the CEA requires the Commission to evaluate the costs and benefits of a proposed regulation in light of efficiency, competitiveness, and financial integrity considerations. The Commission has not identified a specific effect on the efficiency and financial integrity of markets as a result of the proposed regulations. There may be a minor impact from termination of an exemption on the competitiveness of futures markets. Foreign futures and options may compete directly or indirectly with contracts listed on DCMs. Due to legal restrictions in foreign jurisdictions, the only way that U.S. customers may access certain foreign contracts may be through an exempt foreign firm. The termination of any exemptive relief therefore may reduce the available options for U.S. market participants.

c. *Price Discovery.* Section 15(a)(2)(C) of the CEA requires the Commission to evaluate the costs and benefits of a proposed regulation in light of price discovery considerations. The Commission believes that the final regulations will not have any significant impact on price discovery.

d. *Sound Risk Management Practices.* Section 15(a)(2)(D) of the CEA requires the Commission to evaluate the costs and benefits of a proposed regulation in light of sound risk management practices. The Commission believes that the final regulations will not have a large impact on the risk management practices of the futures and options industry. However, to the extent that having a transparent process for terminating exemptions issued to foreign regulatory or self-regulatory organizations on behalf of individual firms may encourage an increased offer and sale of contracts that more closely match the hedging needs of particular U.S. market participants, the practice of sound risk management might be improved slightly.

e. *Other Public Interest Considerations.* Section 15(a)(2)(E) of the CEA requires the Commission to evaluate the costs and benefits of a proposed regulation in light of other

[14] Proposal, 84 FR at 32107.

[15] 7 U.S.C. 19(a).

[16] *Id.*

[17] Proposal, 84 FR 32108.

public considerations. The Commission believes that having a transparent process for terminating an exemption from registration will, in the event that the Commission believes such a termination may be warranted, provide an appropriate notice and opportunity to comment to the public, affected persons, exempt § 30.10 firms, and market participants who may be affected by the termination of an order of § 30.10 exemption.

3. Antitrust Considerations

Section 15(b) of the CEA requires the Commission to take into consideration the public interest to be protected by the antitrust laws and endeavor to take the least competitive means of achieving the objectives of the CEA in issuing any order or adopting any Commission regulation. The Commission has determined that the final amendments to § 30.10 have no anticompetitive effects. The final regulation is a procedural rule that will not cause a change in the behavior that would alter the level playing fields of regulated entities.

List of Subjects in 17 CFR Part 30

Consumer protection, Fraud.

For the reasons set forth in the preamble, the Commodity Futures Trading Commission amends 17 CFR part 30 as follows:

PART 30—FOREIGN FUTURES AND OPTIONS TRANSACTIONS

■ 1. The authority citation for part 30 continues to read as follows:

Authority: 7 U.S.C. 1a, 2, 6, 6c, and 12a, unless otherwise noted.

■ 2. Add paragraph (c) to § 30.10 to read as follows:

§ 30.10 Petitions for exemption.

* * * * *

(c)(1) The Commission may, in its discretion and upon its own initiative, terminate the exemptive relief granted to any person pursuant to paragraph (a) of this section, after appropriate notice and an opportunity to respond, if the Commission determines that:

(i) There is a material change or omission in the facts and circumstances pursuant to which relief was granted that demonstrate that the standards set forth in appendix A to this part forming the basis for granting such relief are no longer met; or

(ii) The continued effectiveness of any such exemptive relief would be contrary to the public interest or inconsistent with the purposes of the exemption under paragraph (a) of this section; or

(iii) The arrangements in place for the sharing of information with the Commission do not warrant continuation of the exemptive relief granted.

(2) The Commission shall provide written notification to the affected party of its intention to terminate an exemption pursuant to paragraph (a) of this section and the basis for that intention. Such written notification also shall be published prominently on the Commission's website.

(3) The affected party may respond to the notification in writing no later than 30 business days following the receipt of the notification, or at such time as the Commission permits in writing. Any other person may respond to the notification in writing no later than 30 business days following the publication on the Commission's website of the written notice issued to the affected party, or at such time as the Commission permits in writing.

(4) If, after providing any affected person appropriate notice and opportunity to respond, the Commission determines that relief pursuant to paragraph (a) of this section is no longer warranted, the Commission shall notify the person of such determination in writing, including the particular reasons why relief is no longer warranted, and issue an Order Terminating Exemptive Relief. Any Order Terminating Exemptive Relief shall provide an appropriate timeframe for the orderly transfer or close out of any accounts held by U.S. customers impacted by such an Order.

(5) Any person whose relief has been terminated may apply for exemptive relief 360 days after the issuance of the Order Terminating Exemptive Relief if the deficiency causing the revocation has been cured or relevant facts and circumstances have changed.

Issued in Washington, DC, on March 9, 2020, by the Commission.

Robert Sidman,

Deputy Secretary of the Commission.

Note: The following appendix will not appear in the Code of Federal Regulations.

Appendix to Foreign Futures and Options Transactions—Commission Voting Summary

On this matter, Chairman Tarbert and Commissioners Quintenz, Behnam, Stump, and Berkovitz voted in the affirmative. No Commissioner voted in the negative.

[FR Doc. 2020–05097 Filed 3–17–20; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

DEPARTMENT OF THE TREASURY

19 CFR Part 12

[CBP Dec. 20–04]

RIN 1515–AE53

Extension of Import Restrictions on Archaeological Material and Imposition of Import Restrictions on Ecclesiastical Ethnological Material From El Salvador

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security; Department of the Treasury.

ACTION: Final rule.

SUMMARY: This document amends the U.S. Customs and Border Protection (CBP) regulations to reflect an extension of import restrictions on certain archaeological material from the Republic of El Salvador (El Salvador). The document further amends the Designated List contained in T.D. 95–20, which describes the types of articles to which the import restrictions apply, to reflect the addition of certain ecclesiastical ethnological material. The import restrictions, which were last extended by CBP Dec. 15–05, were due to expire on March 8, 2020, unless extended. The Assistant Secretary for Educational and Cultural Affairs, United States Department of State, has determined that conditions continue to warrant the imposition of import restrictions on archeological material from El Salvador. Additionally, the Assistant Secretary for Educational and Cultural Affairs, United States Department of State, has made the requisite determinations for adding import restrictions on certain categories of ecclesiastical ethnological material from the Colonial period through the first half of the twentieth century. On March 2, 2020, the Government of the United States and the Government of El Salvador entered into a Memorandum of Understanding (MOU) that supersedes the existing agreement that first became effective on March 8, 1995. Pursuant to the new MOU, the import restrictions for archaeological material will remain in effect for an additional five years until March 2, 2025. The new MOU further covers import restrictions on ecclesiastical ethnological material until March 2, 2025.

DATES: Effective March 16, 2020.

FOR FURTHER INFORMATION CONTACT: For legal aspects, Lisa L. Burley, Chief,

Cargo Security, Carriers and Restricted Merchandise Branch, Regulations and Rulings, Office of Trade, (202) 325–0300, *otrrculturalproperty@cbp.dhs.gov.* For operational aspects, Genevieve S. Dozier, Management and Program Analyst, Commercial Targeting and Analysis Center, Trade Policy and Programs, Office of Trade, (202) 945–2952, *CTAC@cbp.dhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

Pursuant to the Convention on Cultural Property Implementation Act, Public Law 97–446, 19 U.S.C. 2601 *et seq.* (hereinafter, ''the Cultural Property Implementation Act,'' or ''the Act''), which implements the 1970 United Nations Educational, Scientific and Cultural Organization (UNESCO) Convention on the Means of Prohibiting and Preventing the Illicit Import, Export and Transfer of Ownership of Cultural Property (823 U.N.T.S. 231 (1972)), the United States entered into a bilateral agreement with the Republic of El Salvador (El Salvador) on March 8, 1995, concerning the imposition of import restrictions on certain categories of archaeological material from El Salvador's Pre-Hispanic cultures and ranging in date from approximately 8000 B.C. to 1550 A.D. On March 10, 1995, the former U.S. Customs Service (now U.S. Customs and Border Protection (CBP)) published T.D. 95–20 in the **Federal Register** (60 FR 13352), which amended § 12.104g(a) of title 19 of the Code of Federal Regulations (19 CFR 12.104g(a)) to reflect the imposition of these import restrictions and included a list designating the types of archaeological material covered by the restrictions.

Import restrictions listed at 19 CFR 12.104g(a) are effective for no more than five years beginning on the date on which the agreement enters into force with respect to the United States. This period may be extended for additional periods of not more than five years if it is determined that the factors which justified the initial agreement still pertain and no cause for suspension of the agreement exists. *See* 19 CFR 12.104g(a).

Since the initial notice was published on March 10, 1995, the import restrictions were subsequently extended four (4) times. First, on March 9, 2000, following the exchange of diplomatic notes, the former U.S. Customs Service (now CBP), published T.D. 00–16 in the **Federal Register** (65 FR 12470) to extend the import restrictions for a period of five years to March 8, 2005. Second, on March 9, 2005, following the exchange of diplomatic notes, CBP published CBP Dec. 05–10 in the **Federal Register** (70 FR 11539) to extend the import restriction for an additional five-year period to March 8, 2010. Third, on March 8, 2010, following the exchange of diplomatic notes, CBP published CBP Dec. 10–01 in the **Federal Register** (75 FR 10411) to extend the import restriction for an additional period of five years to March 8, 2015. Fourth, on March 6, 2015, following the exchange of diplomatic notes, CBP published CBP Dec. 15–05 in the **Federal Register** (80 FR 12080) to reflect the extension of the import restrictions for an additional five-year period to March 8, 2020.

On June 5, 2019, the United States Department of State proposed in the **Federal Register** (84 FR 26174) to extend the Memorandum of Understanding (MOU) between the United States and El Salvador concerning the imposition of import restrictions on certain categories of archeological material from the Pre-Hispanic Cultures of El Salvador.

On November 7, 2019, after consultation with and recommendations by the Cultural Property Advisory Committee, the Assistant Secretary for Educational and Cultural Affairs, United States Department of State, determined that: (1) El Salvador's cultural heritage continues to be in jeopardy from pillage of Pre-Hispanic archeological resources and that the import restrictions should be extended for an additional five years; and (2) El Salvador's cultural heritage is in jeopardy from pillage of certain types of ecclesiastical ethnological material from the Colonial period through the first half of the twentieth century and import restrictions on such types of ecclesiastical ethnological material should be imposed.

On March 2, 2020, the Government of the United States and Government of El Salvador entered into a MOU, titled ''Memorandum of Understanding between the Government of the United States of America and the Government of the Republic of El Salvador Concerning the Imposition of Import Restrictions on Categories of Archaeological and Ethnological Material of the Republic of El Salvador.'' The new MOU supersedes the existing agreement that first became effective on March 8, 1995. Pursuant to the new MOU, the import restrictions for archaeological material will remain in effect for an additional five years until March 2, 2025. The new MOU further covers import restrictions on certain categories of ecclesiastical ethnological material (from the Colonial period through the first half of the twentieth century ranging in date from approximately A.D. 1525 to 1950) until March 2, 2025.

Accordingly, CBP is amending 19 CFR 12.104g(a) to reflect the extension of the import restrictions, and the Designated List of cultural property described in T.D. 95–20 by adding certain categories of ecclesiastical ethnological material from El Salvador from the Colonial period through the first half of the twentieth century ranging in date from approximately A.D. 1525 to 1950, as set forth below. The restrictions on the importation of archaeological and ecclesiastical ethnological material will be in effect through March 2, 2025. Importation of such material from El Salvador will be restricted through that date unless the conditions set forth in 19 U.S.C. 2606 and 19 CFR 12.104c are met.

The Designated List and additional information may also be found at the following website address: *https://eca.state.gov/cultural-heritage-center/cultural-property-advisory-committee/current-import-restrictions* by selecting the material for ''El Salvador.''

Designated List of Archaeological and Ecclesiastical Ethnological Material of El Salvador

The Designated List contained in T.D. 95–20, which describes the types of articles to which the import restrictions apply, is amended to reflect the addition of certain ecclesiastical ethnological material to the Designated List. In order to clarify certain provisions of the Designated List contained in T.D. 95–20, the amendment also includes minor revisions to the language, organization, and numbering of the Designated List. For the reader's convenience, CBP is reproducing the Designated List contained in T.D. 95–20 in its entirety, with the changes, below.

The Designated List includes archaeological material from El Salvador ranging in date from approximately 8000 B.C. to A.D. 1550, and ecclesiastical ethnological material from El Salvador from the Colonial period through the first half of the twentieth century ranging in date from approximately A.D. 1525 to 1950.

Categories of Material

I. Archaeological Material
  A. Figurines
  B. Other Small Ceramic Artifacts
  C. Ceramic Vessels
  D. Ceramic Drums
  E. Incense Burners
  F. Mushroom Effigies
  G. Stone Sculptures
  H. Small Stone Artifacts
  I. Metal Artifacts
II. Ethnological Material

A. Paintings
B. Sculptures
C. Furniture
D. Metalwork
E. Textiles
F. Documents and Manuscripts

I. Archaeological Material

Archaeological material covered by the MOU includes material from El Salvador ranging in date from approximately 8000 B.C. to A.D. 1550. Examples of archaeological material covered by the MOU include, but are not limited to, the following objects:

Simplified Chronology [1]

Archaic period: c. 8000–1700 B.C.
Preclassic period: 1700 B.C.–A.D. 200
Early Preclassic: 1700–800 B.C.
Middle Preclassic: 800–400 B.C.
Late Preclassic: 400 B.C.–A.D. 200
Classic period: 200 B.C.–A.D. 900
Protoclassic: 200 B.C.–A.D. 200
Early Classic: A.D. 200–600
Late Classic: A.D. 600–900
Terminal Classic: A.D. 800–900
Postclassic period: A.D. 900–1524
Early Postclassic: A.D. 900–1200
Late Postclassic: A.D. 1200–1524
Protohistoric: c. A.D. 1400–1550

A. Figurines

1. Preclassic Figurines

Most are solid ceramic figurines representing women with broad torsos and thighs, and small or virtually flat breasts. These are portrayed in a sitting or standing position. The eyes and mouth were typically represented by jabbing small holes into the still wet clay (punctation), many times with two or three holes used to depict each eye. Although the bodies are crafted without much detail, elaborate coiffures are commonly shown.

a. *Dating:* Most Preclassic figurines date to the Late Preclassic (corresponding to the Chul and Caynac Ceramic Complexes of western El Salvador, and the Uapala Phase of eastern El Salvador).

b. *Appearance:* Often cream to white, but may also be red or brown (ranging from dark brown to tan). Usually of very fine textured clay.

c. *Size:* Most range between 4 in (10 cm) to 8 in (20 cm) in height. Examples smaller than about 4 in (10 cm) may be perforated for use as pendants. Rare figurines of 16 in (40 cm) or more in height have been reported.

d. *Important Variants:* Some of the larger figurines are hollow rather than solid. Very rare examples have movable arms, with sockets set into the shoulders and separate arm pieces that were actuated by means of strings. Some figurines depict women cradling infants. Whistle mechanisms are very rarely present. Painted designs in black or other colors are very rare on these figurines.

e. *Formal Names:* Bolinas figurines (Stanley H. Boggs, ''Pre-Maya Costumes and Coiffures'' in *Americas* 25(2): 19–24, Organization of American States, Washington, DC, United States (1973) (hereinafter, referred to as ''Boggs 1973a'')); Kulil, Xiquin, and Tat Complex figurines (Bruce H. Dahlin, ''Figurines'' in *The Prehistory of Chalchuapa, El Salvador, Vol. 2,* University of Pennsylvania Press, Philadelphia, Pennsylvania, United States (Robert A. Sharer ed. 1978) (hereinafter, referred to as ''Dahlin 1978'')); Quelepa Figurine Types 1 and 2 (E. Wyllys Andrews, V., ''The Archaeology of Quelepa, EI Salvador'' in *Middle American Research Institute* 42, Tulane University, New Orleans, Louisiana, United States (1976) (hereinafter, referred to as ''Andrews 1976'')).

2. Lepa Figurines

Most are solid ceramic figurines representing standing humans, while others are animal effigies that function as whistles, whistle flutes, or wheeled figurines incorporating whistle flutes.

a. *Human Figurines:* These figurines have a generally flattened appearance and heads are usually crowned by a broad and narrow headband (or hairdo) resembling a long bar. Eyes are shown by a single punctuation (to represent the pupil) between two ridges, defining the eye itself. Feet are usually split in a ''Y'' shape to help support the figurine. The figurines may be adorned with necklaces shown by a series of clay pellets. Rarely is enough detail included to determine which sex is intended (in such cases, women are usually represented).

b. *Pelleted Tubular Whistle Flutes:* Tubes with a whistle mechanism (blowhole) at one end and a rolling pellet within that produces a continuously varying tone when blown and tilted up and down. Simple bird or monkey heads may be added to the instrument's body.

c. *Wheeled Figurines:* Human or animal effigies with four tabular legs, each with a perforation to accept wooden sticks as axles for the front and rear wheels (the wheels themselves were ceramic discs rarely found together with these artifacts). Decoration is mostly through appliqué using relatively thick strips and pellets of clay.

d. *Animal Effigy Whistle Flutes:* Made from a small sphere of clay with very simple (schematic) appliqué to represent humans, birds, turtles, armadillos, opossums, and other animals. In addition to the whistle mechanism, these have one or two finger holes in their bodies that vary their tone when covered. The most elaborate examples may have punctate and ridge eyes like those found in the Lepa human figurines. May be perforated for suspension.

e. *Dating:* Late Classic Lepa Phase of central and eastern El Salvador, represented in Quelepa, Tehuacán, and other sites.

f. *Appearance:* Usually reddish brown to brick red, with a rough or only moderately smoothed surface. Some have a polished white slip that, when well preserved, may have elaborate designs painted in black, red, and/or yellow. Pelleted tubular whistle flutes have been noted with fugitive (post-firing) white and/or blue paint.

g. *Size:* Most human figurines range in height between 5 in (12 cm) to 10 in (25 cm). Unusually large examples are known to reach 15 in (38 cm) in height, and these tend to bear painted designs more often than the normal sized figurines. The pelleted tubular whistle flutes known are 7 in (18 cm) or slightly shorter in length. The wheeled figurines known range from about 3.5 in (9 cm) to 5 in (13 cm) in length. The animal effigy whistle flutes measure about 2–3 in (5–8 cm) in maximum length.

h. *Important Variants:* Larger figurines may be hollow rather than solid, and may either contain pellets to act as a rattle, or may be equipped with holes for use as a flute (''ocarina'').

i. *Formal Names:* The human figurines have been classed as Lower Lempa Culture figurines (Wolfgang Haberland, ''On Human Figurines from San Marcos Lempa, El Salvador, C.A.'' in *El Mexico Antiguo* 9: 509–524, México, D.F. (1961) (hereinafter, referred to as ''Haberland 1961'')) and as Quelepa Figurine Type 3 (Andrews 1976). The wheeled figurines have been termed Oriental Type (Stanley H. Boggs, ''Figurillas con ruedas de Cihuatán y el Oriente de El Salvador'' in *Colección de Antropología* 3, Dirección de Publicaciones, Ministerio de Educación, San Salvador, El Salvador (1973) (hereinafter, referred to as ''Boggs 1973b'')). The animal effigy whistle flutes have been referred to as Lepa Phase whistles (Andrews 1976; *see also* Stanley H. Boggs, ''Notes on Pre-

[1] This list of terms of time periods and their subdivisions contains some terms that overlap and are used to distinguish pivotal intervals in regional prehistory (these terms are: Protoclassic, Terminal Classic, and Protohistoric). Different references may vary slightly as to the beginning and end dates for the periods listed.

Columbian Wind Instruments from El Salvador'' in *Baessler-Archiv* 22, Baessler-Institut, Berlin, Germany (1974) (hereinafter, referred to as ''Boggs 1974'')).

3. Cotzumalhuapa Figurines and Molds

Ceramic figurines, usually hollow and typically mold-made in part (especially heads). About half the known examples represent women, and most of the remainder depict a variety of animals (men are rare). Some representations of plants and furniture (litters) are known. Whistle mechanisms were optional for all forms of Cotzumalhuapa figurines. Pelleted tubular whistle flutes and recently identified Cotzumalhuapa wheeled figurines are also included here.

a. *Molds:* The molds used to produce these figurines were press molds made of coarse textured fired clay, usually brick red or reddish brown in color. The working faces of these molds present a complicated depressed area that produces the impression, while the opposite side of the mold is usually rounded and carelessly finished. A sheet of wet clay was pressed into the mold and then carefully extracted with the impression of, for examples, the front half of a female figurine (the other half was added by hand modeling, as were optional details like headgear if these were absent from the mold used).

b. *Female Figurines:* The figurines representing women have been referred to as ''bell-form'' due to the shape of their conical hollow bases. They usually portray elaborately dressed women, adorned with necklaces, earplugs, and large headgear of variable shape (but often resembling a half moon). The uniformity in portrayal suggests that we are dealing with a personage, and it is not too speculative to suggest that she was an important Cotzumalhuapa goddess. Rare figurines exist where the female's body is covered by cacao pods, indicating a relationship to agricultural production and, in these latter examples, with the intensive production of cacao that has been documented as an important Cotzumalhuapa economic focus. Whistle mechanisms, when present, are usually worked into one shoulder (the larger female figurines tend not to possess whistle mechanisms).

c. *Male Figurines:* The very rare male figurines are known to include representations of warriors (with clubs and shields) and injured or diseased individuals (one example shows an individual with patches of flesh missing from the maxillary area and nose).

d. *Animal Figurines:* Among the animals present in Cotzumalhuapa figurines are parrots, vultures, owls, doves, monkeys, felines (probably jaguars are intended), bats, dogs, deer, frogs or toads, turtles, iguanas, snakes, crocodiles, fish, clams, crabs, and others. These reflect the rich fauna of the Cotzumalhuapa area, which included mangrove lined estuaries, the adjoining coastal plains, and nearby mountain ranges. Monkeys and parrots are, however, the most common animals depicted. Most animal figurines have whistle mechanisms. Because of the complicated forms required for animals, use of molds may sometimes be limited to face areas, and some are entirely hand modeled.

e. *Plant Figurines:* Representations of corn cobs and cacao pods have been found.

f. *Pelleted Tubular Whistle Flutes:* Tubes with a whistle mechanism (blowhole) at one end and a rolling pellet within that produces a continuously varying tone when blown and tilted up and down. One example is apparently a bat effigy, with a bat head and disk (representing the wings) added to the tubular body of the instrument.

g. *Wheeled Figurines:* Cotzumalhuapa wheeled figurines have only recently been identified. One has a tubular body with four tabular supports, each with a perforation to accept the wooden sticks that acted as axles for the front and rear wheels. A mold-made dog head was added to one end of the tube, and a tail to the other.

h. *Other Figurines:* Two figurines have been documented representing the litters that were probably used to transport Cotzumalhuapa elites. They resemble a small rectangular box with a canopy, supported by four spiked feet. A pair of holes at each extreme permitted two sticks to be inserted to act as the carrying poles. On one example, the canopy was modeled to represent the stretched skin of a crocodile arranged with the head at one extreme and the tail at the other, with a spiked crest running between the two. Other Cotzumalhuapa modeled clay artifacts that may be included as figurines include objects resembling scepters, bells, lidded boxes, and plaques with human faces.

i. *Dating:* Late Classic products of the Cotzumalhuapa culture, which in El Salvador included the western coastal plain to the upper drainage of the Paz River. Trade brought examples into Payu Ceramic Complex contexts elsewhere in western and central El Salvador.

j. *Appearance:* Most are brown (from tan through reddish brown) to red (brownish red to brick red), with a coarsely finished to moderately smoothed surface. Rare examples are of Tiquisate Ware (characterized by a very smooth, lustrous, and hard surface, cream to orange in color), and may be ancient imports from the Pacific coast of Guatemala. Traces of paint may be present (blue, black, red, yellow, and white have been documented); the paint was usually applied after firing and tends to be easily eroded. Those parts of figurines made without the benefit of molds tend to be rather carelessly modeled.

k. *Size:* Female figurines usually range in height from 4 in (10 cm) to 12 in (30 cm), but some rare specimens reach 24 in (60 cm) and perhaps more in height. Animal and plant figurines tend to be small, typically ranging from 3 in (8 cm) to 6 in (16 cm) in their maximum dimension, though larger examples occur. The pelleted tubular whistle flute mentioned measures 6 in (16 cm) in length. Wheeled figurines measure 5.5 in (14 cm) in length. The models of litters are approximately 9 in (23 cm) in length.

l. *Important Variants:* Cotzumalhuapa use of clay was very creative and the observer should expect figurine forms not mentioned here.

4. Payu Figurine Flutes and Whistles

Most Payu ceramic figurines known are musical instruments that have been classified as whistles, whistle flutes, and flutes (commonly called ''ocarinas''). Although their decoration varies considerably, important hallmarks (when present) are the decorative use of parallel strips of clay (sometimes with longitudinal grooves), and appliqué of clay pellets with a distinctive dimple in their center. Molds were sometimes employed to render the faces of humans and monkeys. Human faces may include details commonly associated with Classic Maya conventions, including cheek decorations (from tattoos or scarification), extension of the bridge of the nose to above eye level, and/or a steeply inclined forehead (representing cranial deformation).

a. *Globular Flutes (''ocarinas''):* Payu figurine globular flutes have a very distinctive construction. Three spheres of clay were joined together in a column or in an ''L'' shape (and pierced at the junctures). The uppermost sphere was equipped with a blowhole. Clay was then packed around this assembly and decorative elements added. All ''L''-shaped flutes known were decorated to represent a standing quadruped animal whose open mouth forms the blowhole. Other (straight) flutes were almost always modeled to represent a human

(either full-body or just the head portion).

b. *Tubular Whistle Flutes:* A tubular form with a whistle mechanism (blowhole) at one end and three to five finger holes along the body of the tube. The appliquéd head and arms of a monkey or human are always present next to the blowhole.

c. *Whistle Flutes:* A small, spherical body with a whistle mechanism and one or two finger holes is hidden to a lesser or greater degree under effigy decoration. This decoration tends to be notably more carefully executed and detailed than Lepa or Cotzumalhuapa examples. Examples include effigies of humans (full-body or heads), monkeys, dogs, birds, and reptiles. Smaller whistle flutes may be perforated for suspension.

d. *Dating:* An artifact class belonging to the assemblage associated with the Payu Ceramic Complex (Late Classic Period).

e. *Appearance:* Most Payu figurines are of medium textured clay with a moderately smoothed surface (and almost always unslipped). Color is usually reddish brown but may range from tan to brick red. Traces of paint are rare and may include blue-green, white, yellow, red, or black. Painted decoration, when present, was usually added after firing and tends to easily wear away.

f. *Size:* Globular flutes: 3–8 in (8–21 cm); tubular whistle flutes: 6–8 in (15–21 cm); whistle flutes: 2–8 in (5–20 cm).

g. *Formal Names:* None. Many examples are illustrated in Boggs 1974 (noted as Late Classic, from western and part of central El Salvador).

5. Guazapa Figurines

Early Postclassic ceramic figurines whose style is derived from central Mexico and form part of the Guazapa Phase of central and western El Salvador. The Guazapa Phase has been interpreted as marking the large-scale migration of Nahua speakers into this area, these being the ancestors of the historical Pipil.

a. *Mazapan-Related Figurines:* Very flat figurines whose rendition of the human figure has been compared to gingerbread cookies. These objects were made by pressing a sheet of clay into a mold, obtaining a thin (0.75–1 in (2–3 cm)) solid figurine. The rear portion of the figurine is left unfinished and may exhibit finger marks from when the clay was pressed into its mold. The front displays a woman with a blouse with a triangular front, coming to a point in the middle of the waist. This type of blouse was referred to as a *quechquemitl* in central Mexico at the time of the Conquest, when its use was restricted to images of goddesses and goddess impersonators. These figurines are named for their close similarity to figurines of the Mazapan (Toltec) Phase of central Mexico.

b. *Toad Effigies:* Hand modeled large hollow toad effigies. They are usually shown as sitting as erect as possible for a toad, looking upwards. The front and rear of the toad's body is decorated with strips and buttons of clay meant to represent festive ribbons and bows. The tongue may be shown hanging from the mouth. In Postclassic Nahua mythology, toads were considered Tlaloc's (the rain god) helpers, and it was they who announced the coming of the rains (the extended tongues are probably meant to represent their thirsty anticipation of rain). Due to this association, some examples of toad effigies include two rings around the eyes (a diagnostic trait of Tlaloc himself).

c. *Tlaloc Bottles:* Bottles with a more or less spherical body crowned by a straight tubular neck with a flat, flaring rim. The body is decorated with the face of the rain god Tlaloc whose most distinctive trait is a ring around each eye. Many Tlaloc Bottles are in fact plugged in the neck or body and could not have actually functioned as vessels. Tlaloc was considered to dwell in the mountain peaks and pour out the rains from a bottle. These artifacts were probably household votive images of that bottle.

d. *Very Large Effigy Figurines or Statues:* Hand modeled hollow figurines representing jaguars, gods, or god impersonators. The larger examples reach life size and may truly be considered ceramic statuary (in any case, they have been included under ''Figurines'' to facilitate discussion). Known examples of gods or god impersonators represent the gods Tlaloc (identifiable by the rings around his eyes), Mictlantecutli (represented as a skeletal personage), and Xipe Totec (portrayed as wearing a flayed human skin). The largest figures may be crafted in several mating parts (for example, a Xipe Totec effigy was made in two large halves joining at the waist, with a separate head). Seventeen jaguar effigies were found in one excavation at Cihuatán; all of these portray a jaguar sitting on its haunches, decorated with necklaces and a few bulbous objects placed on different parts of the body.

e. *Small Solid Figurines:* Hand modeled figurines of humans that are usually solid or mostly so, and that occasionally employed molds to form the face. Most appear to represent males who may carry war equipment (such as a dart thrower or *atlatl*) and large headgear. These figurines tend to be relatively small and crudely modeled.

f. *Wheeled Figurines:* Small wheeled figurine, consisting of a tubular hollow body with four tabular supports, each with a hole to accept wooden sticks acting as axles for the front and rear wheels. The wheels are flat ceramic disks. A tail was added to one end of the tubular body and a head to the other. Examples are known with deer heads with antlers and dog heads with tongue extended over the lower lip.

g. *Dating:* Artifacts of the Early Postclassic Guazapa Phase of central and western El Salvador (at Cihuatán, Igualtepeque, El Cajete, Ulata, Santa María, Pueblo Viejo Las Marías, and other sites).

h. *Appearance:* Generally reddish brown to brick red, but may be as light as tan in color. The surface may be smoothed but not polished and has a sandy texture. Many give the impression of having been hastily made. Traces of white, black, blue, yellow, and/or red fugitive paint have been found on some figurines.

i. *Size:* Height of Mazapan-related figurines: 6–10 in (15–25 cm); height of toad effigies: 6–9 in (15–23 cm); height of Tlaloc bottles: 4–10 in (10–25 cm); height of very large effigy figurines or statues: 24–55 in (61–140 cm); height of small solid figurines: 6–18 in (15–30 cm); length of wheeled figurines: 5.5–8.5 in (14–22 cm).

j. *Formal Names:* Encompassed by the Guazapa Phase, the type site of which is Cihuatán (*see* Stanley H. Boggs, ''A Human-Effigy Figure from Chalchuapa, El Salvador'' in *Notes on Middle American Archaeology and Ethnology* 31, Carnegie Institution of Washington, Washington, DC, United States (1944) (hereinafter, referred to as ''Boggs 1944''); Stanley H. Boggs, ''Apuntes sobre varios objetos de barro procedentes de Los Guapotes en El Lago de Guija'' in *Antropología e Historia de Guatemala* 15(1), Instituto de Antropología e Historia, Guatemala (1963) (hereinafter, referred to as ''Boggs 1963''); Boggs 1973b; Stanley H. Boggs, ''Antigüedades salvadoreñas errantes: dos Xipe Totecs del lago de Güija'' in *Anales del Museo Nacional ''David J. Guzmán''* 49, Dirección de Publicaciones, Ministerio de Educación, San Salvador, El Salvador (1976) (hereinafter, referred to as ''Boggs 1976''); Karen Olson Bruhns, ''Cihuatán: An Early Postclassic Town of El Salvador, the 1977–78 Excavations'' in *Monographs in Anthropology* 5, The Museum of Anthropology, University of Missouri, Columbia, Missouri, United States (1980) (hereinafter, referred to as ''Bruhns 1980''); William R. Fowler, Jr.,

The Pipil-Nicarao of Central America (unpublished dissertation) (on file with Department of Anthropology, University of Calgary, Canada (1981) (hereinafter, referred to as ''Fowler 1981''); William R. Fowler, Jr., ''The Figurines of Cihuatán, El Salvador'' in *The New World Figurine Project, Vol.* 1, Research Press, Provo, Utah, United States (Terry Stocker ed. 1990) (hereinafter, referred to as ''Fowler 1990'')).

B. Other Small Ceramic Artifacts

1. Spindle Whorls or Malacates

Small ceramic disc-shaped artifacts with a central perforation. As viewed in section, these are thicker towards the center. They may have incised or mold-made decoration. These are often mistaken for ceramic beads and many may be strung together for transport or display.

a. *Dating:* Late Classic to Protohistoric Periods. Different varieties are documented in relation to Late Classic Phases and ceramic complexes (Lepa, Payu, Tamasha) through the Postclassic (Guazapa, Cuscatlán, and others).

b. *Appearance:* Carefully formed and smoothed. Many were slipped, and run the full range of black through brown through red. Fugitive white paint has been noted as a rare filler for incised designs.

c. *Size:* 0.8–1.2 in (2.1–3.2 cm) in diameter. Holes are always close to 0.25 in (0.6 cm) in diameter.

d. *Formal Names:* Referred to as spindle whorls or malacates (*see, e.g.,* John M. Longyear, III, ''Archaeological Investigations in El Salvador'' in *Memoirs of the Peabody Museum of Archaeology and Ethnology* 9(2), Harvard University, Cambridge, United States (1944) (hereinafter, referred to as ''Longyear 1944''); Robert J. Sharer, ed., *The Prehistory of Chalchuapa, El Salvador,* University of Pennsylvania, Philadelphia, Pennsylvania, United States (1978) (hereinafter, referred to as ''Sharer 1978''); Andrews 1976).

2. Ceramic Seals

Ceramic seals present a high-relief pattern on clay surface and are thought to have been used with paint to stamp designs for body and/or textile decoration. Some were used to impress designs on still-wet pottery objects. Some seals have been found still covered with red pigment. Seals may be flat, with a spike handle on the rear, or cylindrical and used by rolling. Cylinder seals usually have a central perforation that would have allowed a stick to be passed through and facilitate their use like rolling pins.

a. *Dating:* To date, seals have been found in El Salvador in contexts ranging from the Late Preclassic and Late Classic Periods (in relation to the Chul, Caynac and Payu Ceramic Complexes and the Tamasha Phase).

b. *Appearance:* Well-smoothed and sometimes slipped surfaces. Color ranges from black-brown through reddish-brown and red.

c. *Size:* Flat seals: 1.2–5 in (3–13 cm) in diameter; cylinder seals may be 2.4–5 in (6–12 cm) in length.

d. *Formal Names:* Usually referred to as seals or stamps, flat or cylindrical (*see* Sharer 1978; Arthur A. Demarest, ''The Archaeology of Santa Leticia and the Rise of the Maya Civilization'' in *Publication* 52, Middle American Research Institute, Tulane University, New Orleans, Louisiana, United States (1986) (hereinafter, referred to as ''Demarest 1986''); Paul E. Amaroli, *Informe preliminar de las excavaciones arqueológicas en Cara Sucia, departamento de Ahuachapán, El Salvador* (unpublished manuscript) (on file with Dirección de Patrimonio Cultural, San Salvador, El Salvador) (1987) (hereinafter, referred to as ''Amaroli 1987'').

3. Miniatures

Very small ceramic objects made in the form of jars or flasks. Often made of a very fine cream colored ceramic. These may be modeled to resemble squash effigies, or may include stamped designs of Maya glyphs, human forms, or animals. Miniature vessels often contain residuals of red pigment. Late Classic Period.

a. *Size:* 1.5–4 in (4–10 cm) in height.

b. *Formal Names:* None.

4. Spools

This category includes several varieties of spool-shaped artifacts that functioned as earspools and as labrets. Often a short tab extends from one side, while the other may have modeled (and sometimes mold-made) decoration. Alternatively, the spool sides may have incised decoration.

a. *Dating:* Early Preclassic through Postclassic Periods (Sharer 1978; Amaroli 1987).

b. *Size:* Normally do not exceed 1.3 in (3.4 cm) in their maximum dimension.

C. Ceramic Vessels

1. Polychrome Vessels

a. *Copador Polychrome Vessels:* Hemispherical bowls, bowls with composite walls, cylindrical vases, and jars with painted designs in red, black, and optionally yellowish orange on a cream to light orange base. The red paint used is almost always specular (small flecks of crystals flash as the vessel is moved in strong light). Copador paste is cream colored (or sometimes very light brown) and is not very hard or dense. Designs (usually on the exterior) may include bands of motifs derived from Maya glyphs, seated individuals, individuals in a swimming position, melon-like stripes, birds or other animals, and others. Rare examples have excavated lines or patterns. Copador Polychrome may usually be distinguished on the basis of its specular red paint and cream colored paste.

i. *Dating:* Late Classic Period (defined as a member of the Payu Ceramic Complex, which is commonly in Tamasha Phase deposits (Cara Sucia)).

ii. *Size:* Bowl diameter may vary from 4–12 in (10–30 cm), the height of cylindrical vases may range from 6–12.5 in (15–32 cm), and jar height ranges from approximately 5–11 in (12–28 cm).

iii. *Formal Names:* Referred to as the Copador Ceramic Group (Sharer 1978).

b. *Gualpopa Polychrome:* This type is closely related to Copador Polychrome, with which it shares a cream colored paste and the hemispherical bowl form (rarer forms in Gualpopa are: Flat bottomed bowls with vertical walls and composite walled bowls). Designs in Gualpopa are painted in red (which, unlike the Copador, are not specular) and black on a cream-orange base. Gualpopa motifs are simpler than Copador. Most common designs are geometric designs (spirals, ''melon'' bands, chevrons, and others), but repeating birds, monkeys, or designs derived from Maya glyphs may be found.

i. *Dating:* Late Classic, especially the first part of this period. Defined as a member of the Payu Ceramic Complex.

ii. *Size:* Diameters range from 6–15 in (16–38 cm).

iii. *Formal Names:* Termed as the Gualpopa Ceramic Group (Sharer 1978).

c. *Arambala Polychrome:* Formerly referred to as ''false Copador'' due to its close resemblance to Copador Polychrome. Arambala may be differentiated from Copador by its reddish paste (contrasting with Copador's cream paste) and the use of a dull red paint (rather than Copador's specular red paint). Apart from these two differences, however, Arambala closely duplicates Copador's repertoire of vessel forms, dimensions, and decoration (which are described above). A cream-orange slip was added over Arambala's reddish paste to approximate Copador's base color, but this slip often has a streaky appearance.

i. *Dating:* Late Classic Period. A member of the Payu Ceramic Complex

and present in the Tamasha Phase of Cara Sucia.

ii. *Size:* See the description for Copador Polychrome.

iii. *Formal Names:* Defined as the Arambala Ceramic Group (Sharer 1978).

d. *Campana Polychrome Vessels:* Flat bottomed bowls with flaring walls, usually large. Provided with four hollow supports that may take the form of pinched cylinders or cylinders with human or animal effigies. Intricate painted designs were executed in black-brown, dull red, and orange, on a cream to cream-orange base. A large portrayal of a human or animal is featured on the interior center of these vessels, and the rims often have a distinctive encircling twisted rope and dot design. Some examples have a few curving lines of broad (up to 0.5 in (1.3 cm)) Usulután negative decoration. Campana Polychrome paste is dense, hard, and brick red. Other forms include small bowls without supports, with flat bottoms and flaring walls, and cylindrical vases with bulging and sometimes faceted midsections and occasionally short ring bases. The cylindrical vases usually feature panels on opposing sides of the vessel, with human or animal designs, and may have very short and wide tabular supports.

i. *Dating:* Late Classic Period. Present in association with the Payu Ceramic Complex (Sharer 1978), the Lepa Phase (Andrews 1976), and the Tamasha Phase (Amaroli 1987).

ii. *Size:* The large bowls with supports range from 10–20 in (25–50 cm) in diameter. The small bowls without supports are usually 6–9 in (16–22 cm) in diameter. Cylindrical vases range in height from 7–10 in (18–25 cm).

iii. *Formal Names:* Termed as the Campana Polychrome Ceramic Group (Sharer 1978).

e. *Salua Polychrome:* Mostly cylindrical vases, usually with very short and wide tabular supports. The larger examples may have two opposing modeled head handles, just below the rim, representing monkeys or other animals. Bold designs are painted on a cream to orange base, using different combinations of black, dull red, dark orange, and yellow. The normally invisible paste is brick red. Black was often used to create ample panels (or even to cover almost the entire vessel) as a backdrop for featured designs. The principal designs are strikingly displayed and can include: Mat patterns (*petates*), twisted cord patterns, animals (jaguars, parrots, owls, and others), humans, sea shells, ballcourts (represented by a two or four colored ''I''-shaped drawing), and other motifs. Humans are often arrayed in finely detailed costumes and may be represented playing musical instruments, sowing with a digging stick, armed for battle, seated within a structure, or in other attitudes. A decorative option was to excise or stamp designs in panels or registers.

The remainder of the vessel (or, if a featured motif is lacking, all of the vessel) is decorated with panels and registers with circumferencial bands near the rim and geometric patterns elsewhere. Other vessel forms known for Salua are short cylinders, bowls, convex walled bowls (*i.e.,* with bulging sides), composite walled bowls, and jars. Despite their exceptional decoration, colored stucco was sometimes used to cover areas of Salua vessels (when eroded this stucco leaves chalky traces). Salua vessels have rarely been found filled with red pigment.

i. *Dating:* Late Classic (associated with the Payu Ceramic Complex and the Lepa Phase).

ii. *Size:* The cylindrical vessels grade into vertical walled bowls over a range of heights from 3.5–12.5 in (9–32 cm). Bowl diameters range from 6–12 in (15–30 cm).

iii. *Formal Names:* The name Salua is a local term employed in the National Museum of El Salvador. It has been long recognized that probably several different ceramic groups are lumped under this term, and that at least some of these groups probably correspond with the so-called Ulua or Sula Valley Polychromes of neighboring Honduras (which, in recent years, have been divided among several ceramic groups).[2] Sharer cites Salua as a special group of the Payu complex, termed Special: Polychrome B, and he also mentions the name Salua Polychrome (Sharer 1978). At Quelepa, it was noted as an unnamed ceramic group referred to as Dark Orange and Black on Orange (Andrews 1976). Several examples are illustrated in Longyear 1944 and John M. Longyear, III, ''Archaeological Survey of El Salvador'' in *Handbook of Middle American Indians, Vol. 4,* University of Texas Press, Austin, Texas, United States (Gordon F. Ekholm and Gordon R. Willey eds. 1966) (hereinafter, referred to as ''Longyear 1966'').

f. *Quelepa Polychrome:* Hemispherical and composite wall bowls and jars. Bowls may have basal flanges or slight angle changes near the rim, and small solid or larger hollow supports. Quelepa Polychrome has a hard and very white base (slip) over a fine red paste. On this white base were painted designs in orange (often applied as a wash over most of the vessel), red, and black; very rarely a purple paint may be present. Designs include ''checkerboards'', sunbursts, circles, bands, wavy lines, and others. Animals may be depicted on the interior or exterior (jaguars, birds, and monkeys have been noted).

i. *Dating:* Late Classic (a member of the Lepa Ceramic Complex).

ii. *Size:* Bowls may measure from 4.5–15 in (11–38 cm) in diameter.

iii. *Formal Names:* Termed as the Quelepa Polychrome Ceramic Group in Andrews 1976.

g. *Los Llanitos Polychrome:* Flaring walled bowls, most or all with solid tabular supports (supports may have effigy decoration). A cream colored slip was applied on a red paste. Orange paint was applied to the entire interior of the bowl and in small areas bordered by black on the exterior. In addition to orange and black, colors may include dull red, sepia, and rarely purple. Two designs diagnostic of Los Llanitos Polychrome are a ''five-fingered flame'' and stacks of three or four horizontal bars of decreasing length.

i. *Dating:* Late Classic (a member of the Lepa Ceramic Complex).

ii. *Size:* 7–12.5 in (18–32 cm) in diameter.

iii. *Formal Names:* Termed Los Llanitos Polychrome by Longyear (Longyear 1944) and Los Llanitos Polychrome Ceramic Group by Andrews (Andrews 1976).

h. ''*Chinautla*'' *Polychrome:* Flaring walled bowls with flat bases and three or four hollow conical supports with simple appliqué. Red and black-brown designs were painted over a cream slip in registers, including spirals, stepped frets, bars, and dots.

i. *Dating:* Late Postclassic (a member of the Ahal Ceramic Complex).

ii. Size: 6.5–10 in (17–26 cm) in diameter.

iii. *Formal Names:* First defined in Chalchuapa as the Chinautla Ceramic Group by Sharer (Sharer 1978) due to its similarities with the ''Chinautla Polychrome tradition'' found mostly in the Guatemalan highlands, which is subdivided into several distinct and locally distributed ceramic groups, of which the Chalchuapa variety would be one.

i. *Machacal Purple Polychrome:* Bowls (hemispherical, composite walled, or vertical walled with convex bases). With the exception of vertical walled bowls, these may be supported by ring bases, pedestal bases, or four hollow cylindrical supports. Possesses an orange base slip with red and dark

[2] In comparison with Honduran collections, there is a relative abundance of Salua Polychrome in national and private collections in El Salvador.

purple designs. Purple designs in the form of a horizontal ''S'' on the vessel exterior are common. Vessel bottoms usually have a simple purple design that some people have considered to vaguely resemble a bird. The generous use of purple paint on an orange base slip is a distinctive characteristic of this variety.

i. *Dating:* End of the Early Classic and beginning of the Late Classic.

ii. *Size:* 5–11.5 in (13–29 cm) in diameter.

iii. *Formal Names:* Termed Red and Purple on Orange by Boggs (in Longyear 1944), and Machacal Purple-polychrome by Sharer (Sharer 1978).

j. *Nicoya Polychrome:* Hemispherical bowls, bowls with rounded to almost flat bases and flaring walls (these may have three hollow cylindrical or conical supports with effigy decoration as an option, often in the form of bird heads), cylindrical vases with ring bases, and jars. Red, black, and yellow paint was applied over a very smooth white slip with a ''soapy'' texture. Usually over half of the vessel was left white. Designs include registers with geometric designs, human figures, and others. Rare vessels may have unusual forms and appendages.

i. *Dating:* Early Postclassic.

ii. *Size:* Bowls range from 6–11 in (15–28 cm) in diameter; cylindrical vases range from 6.5–12 in (17–30 cm) in height.

iii. *Formal Names:* Long called Nicoya Polychrome due to its relationship with the different varieties grouped under that name first defined for Nicaragua and Costa Rica. The variety found in El Salvador differs sufficiently from those varieties in forms and decoration to be considered as an additional type.

k. *Chancala Polychrome:* Hemispherical bowls, often slightly flaring from just under the rim. A cream base slip (often streaky in appearance) was painted with designs in brown-black and red. Animals rendered in a distinctive silhouette style were painted on opposing sides of the exterior (monkeys, lizards, and birds seem to be represented), with large solid circles, squares or cross-hatch designs between the two. The upper portion of the exterior body is divided by bands in a register holding step frets, circles, and/or other designs.

i. *Dating:* Late Classic.

ii. *Size:* 6–8 in (15–20 cm) in diameter.

iii. *Formal Names:* Termed Chancala Polychrome by Boggs (Stanley H. Boggs, ''Cerámica clásica del barrio Santa Anita, San Salvador en la colección Orlando de Sola'' in *Anales del Museo Nacional ''David J. Guzmán''* 9 (37–41), Museo Nacional de San Salvador, San Salvador, El Salvador (1972) (hereinafter, referred to as ''Boggs 1972'')).

l. *Salinitas Polychrome:* Known in bowl forms with a streaky cream to orange base slip. Black circumferencial bands define registers that usually enclose alternating spirals and stylized animals outlined in black with orange infilling.

i. *Dating:* Late Classic Period.

ii. *Formal Names:* Termed Salinitas Polychrome by Boggs.

2. Vessels With Usulután Decoration

Here are included several different varieties of ceramics that prominently feature Usulután decoration as their distinctive trait. Usulután decoration is a negative technique, resulting in light-colored lines against a darker background. The light lines were achieved by applying a resist substance and then covering the vessel with a slip that fired a darker color. Since this failed to adhere to the areas with resist, these maintained their lighter shade (a simplified explanation). In its most elaborate version, the resist substance was applied with a multiple brush with as many as seven small brushes fastened in a row, allowing the creation of swirling parallel lines. The base color on these vessels ranges from salmon pink to dark yellow, with the lines being a lighter shade of the same. Some varieties have red paint added as rim bands or (in the case of the Chilanga Ceramic Group) simple designs. Formal names for the ceramic groups considered here are: Jicalapa, Puxtla, Izalco, and Chilanga (Sharer 1978, Demarest 1986, Andrews 1976).

3. Plumbate Vessels

Unpainted vessels with a glazed appearance. Surface color ranges from dark brown-black to lead-colored to salmon-orange, and sometimes all are found on a single vessel. Some areas may be iridescent. This is an extremely hard ceramic and ''rings'' when tapped. Vessel forms include a variety of forms of jars, bowls, cylindrical vases, and may even include figurines. Effigy decoration is common.

a. *Dating:* Terminal Classic (San Juan variety) and Early Postclassic (Tohil variety).

b. *Formal Names:* Both San Juan and Tohil varieties [3] are found in El Salvador (Sharer 1978).

[3] One third of all Tohil vessels recorded in the only pan-Mesoamerican inventory to date were from El Salvador (Ann O. Shepard, ''Plumbate: A Mesoamerican Trade Ware'' in *Publication* 573, Carnegie Institution of Washington, Washington, DC, United States (1948)).

4. Olocuilta Orange and Santa Tecla Red Vessels

These two distinctive varieties of Late Preclassic ceramic vessels share many forms and types of decoration. Forms include a variety of bowls that may have very wide everted rims with scalloped and incised designs (in extreme cases, the rims may be extended to form fish or other animal effigies when viewed from above). Bowls may also include faceted flanges. Some bowls may take the form of toad effigies. Usulután decoration (very often poorly preserved) may be present. The Santa Tecla Red variety is distinguished by its dense dark red slip, while Olocuilta Orange has a light orange slip (often with a powdery texture when slightly eroded). Santa Tecla Red may have graphite rubbed into grooves.

a. *Dating:* Late Preclassic (Chul and Caynac Ceramic Complexes).

b. *Formal Names:* Santa Tecla and Olocuilta Ceramic Groups (Sharer 1978; Demarest 1986).[4]

5. Incised or Excised Vessels

Here are considered different varieties of ceramic vessels whose salient visual trait is decoration based on incision or excision.

a. *Pinos:* Pinos vessels have a smooth streaky black to brown slip with (post-slip) incisions on the exterior forming geometric designs. These incisions are sometimes filled with red or white pigment. Forms include a variety of bowl forms. Defined as part of the Chul and Caynac Ceramic Complexes of the Late Preclassic Period (Sharer 1978; Demarest 1986).

b. *Lolotique:* A variety of bowl forms of a dark and dull red color with fine post-slip incised geometric patterns. Defined as part of the Chul and Caynac Ceramic Complexes of the Late Preclassic Period (Sharer 1978; Demarest 1986).

c. *Chalate Carved:* Cylindrical vessels with a band of false glyphs or geometric designs carved below the rim. Details within this excavated band may be emphasized with incision. Vessel bodies are usually tan colored, and cream slip was sometimes added over the exterior, avoiding the carved band which was sometimes painted with red slip. When the cream slip is present, negative designs of dots, circles, water lilies, or egrets may be barely visible on the vessel body. The name of this Late Classic type is provisional and was proposed by Boggs based on its abundance in the Chalatenango area.

[4] In these sources, ''Olocuilta'' (which is the name of a Salvadoran town) was misspelled ''Olocuitla''.

d. *Red Excised:* Cylindrical vessels with a band of false glyphs or geometric decoration excised below the rim and vertical excised grooves usually covering the rest of the exterior, sometimes with two opposing excised panels representing animal heads or other designs. Slipped with a dark red-orange color. Short solid tabular or nubbin supports may be present. Provisional name for a Late Classic type common in central El Salvador.

e. *Cotzumalhuapa Incised Cylindrical Vases:* Cylindrical vases, orange to brown in color, with fine incision including geometric motifs and monkeys. The rim area is distinguished by a band or groove. Late Classic Period.

6. Vessels With Red Decoration

Here are grouped together varieties of ceramic vessels whose principal decoration was executed in red paint.

a. *Marihua Red on Buff:* Forms include: Hemispherical bowls, bowls with rounded bases and flaring walls (these usually have three hollow or cylindrical supports, sometimes in the form of bird heads), and jars with three handles. Broad red lines form geometric designs on the buff colored interior of bowls and the exterior of jars. Designs include arcs, crosses, step frets, *ehecatcozcatl* (split snail shell motif), and others. Very rare are finely incised designs in a band on the exterior of bowls. Postclassic Period (Wolfgang Haberland, ''Marihua Red-on-Buff and the Pipil Question'' in *Ethnos* 29 (1–2), National Museum of Ethnography, Stockholm, Sweden (1964) (hereinafter, referred to as ''Haberland 1964'')).

b. *Guarumal:* Almost all known examples are jars. Part of the jar exterior (reddish brown in color) is painted with a dense and hard red paint that is finely crazed. The paint may cover the upper portion of vessels, or may be distributed as panels, large dots or arcs. Rarely the entire vessel exterior is covered in red. A decorative option was to apply white paint in circles (applied with a hollow cane) and/or zigzagging lines. This white paint is also very hard and was applied over red painted areas. A small rabbit appliqué may appear on the vessel body. Late Classic Period (Marilyn P. Beaudry, ''The Ceramics of the Zapotitán Valley'' in *Archaeology and Volcanism in Central America: The Zapotitán Valley of El Salvador,* University of Texas Press, Austin, Texas, United States (Payson D. Sheets ed. 1983) (hereinafter, referred to as ''Beaudry 1983'')).

c. *Delirio Red on White:* Hemispherical bowls (sometimes made into an *armadillo* effigy by means of a shingled exterior and appliquéd head and tail), bowls with flat or slightly rounded bottoms and flaring walls (these may have hollow cylindrical supports), jars (which may have a pair of effigy head handles below the rim), and other minor forms. A hard white slip was painted in red with very intricate geometric designs. Naturalistic forms are very rare. Late Classic Period (Lepa Ceramic Complex—Andrews 1976).

d. *Cara Sucia Red Painted:* Jars with dull red-orange paint over a cream-orange slip. The lower body is divided by vertical pairs of bands. Birds or other motifs may be painted on the shoulder of the vessel. Late Classic Period.

7. Jars With Modeled Effigy Faces

Here are grouped together different varieties of ceramic jars that share the presence of effigy faces or heads applied to the vessel neck. Motifs include: Old man, man with goatee and closed eyes, monkey, bird, and schematic humans.

8. Tiquisate Vessels

Tiquisate vessels are entirely orange (ranging from light cream-orange to deep orange in color). Their surface is very hard and may ''ring'' when tapped. Vessel forms include hemispherical bowls and cylindrical vases. Decoration may take the form of rows of bosses, incised geometric designs, or stamped scenes of humans, animal heads, twisted bands, or other designs. Late Classic.

9. Fine Paste Vessels

Forms include small flat bottomed bowls with vertical walls and hollow rattle supports, and piriform vessels with ring bases. Vessel walls are very thin and ''ring'' when tapped. An orange may be applied to the vessel with the exception of the base. Fine incising may be found on the exterior of bowls and may retain white and blue post-fire paint. Terminal Classic Period.

10. Cara Sucia Pedestal-Based Bowls

A distinctive type of bowl with a tall pedestal base. The bowls often have a basal flange, and red painted zones are sometimes found on the interior. Late Classic Period.

11. Stuccoed Vessels

Here are grouped a variety of vessel forms and types whose common denominator for the purposes at hand is the presence of stuccoed decoration. The stucco involved is usually a white kaolin clay with blue, blue-green, red, yellow, or brown pigment mixed in, and probably had (originally) an organic binder or agglutinate. Since that binder long since ceased to function, the stuccoed decoration tends to be very fragile. Designs are usually simple bands or geometric motifs, but occasionally human or animal figures may be represented. Entirely stuccoed vessels seem to be most common in the Late Classic, and especially in the Terminal Classic.

12. Guazapa Scraped Slip Vessels

Jars with a brown body over which was applied a cream colored slip that was finger dragged (like finger painting) while it was still wet, creating curving or wavy designs. A reddish-orange wash was sometimes applied over the scraped slip. Early and Late Classic Periods.

13. Ancient Imports

Late Classic Palmar and Other Lowland Maya Ceramics Several vessels of so-called ''Peten Glossware'' have been found in El Salvador that include the formally defined Palmar Ceramic Group, and may also include examples of the Saxche Ceramic Group and others (Sharer 1978). To date, three of such vessels have been found in scientific excavations (one in a Tazumal tomb in the 1940s, a Palmar vessel in an offering with an eccentric flint in San Andrés in the 1970s, and a Palmar vessel in a grave on the outskirts of San Salvador in 1993). Several others have been documented in looting situations, including three recorded by Sharer (Sharer 1978), and in private collections. Although these vessels were not made in the territory of El Salvador, they were ancient imports, and, as such, form part of the Salvadoran cultural heritage, providing important testimony relative to long-distance social and economic relationships.

Forms include bowls with flat or slightly rounded bottoms and walls ranging from slightly flaring (nearly vertical) to broadly flaring walls, shallow simple bowls, tecomates (spherical forms with a small orifice), and cylindrical vases. Bowls may have ring bases, hollow cylindrical supports, or other forms of supports. Decoration consists of an orange or cream base slip over which were painted designs in black, red, and sometimes yellow. Designs include: Glyph bands, humans standing, seated, dancing, or in other attitudes, heads (human, animal, God K, and others), animals in different positions, and other themes rendered in Late Classic Lowland Maya style.

D. Ceramic Drums

Ceramic drums comprise a globular body with a short rim on one extreme (over which the drum surface was stretched) and a long open shaft on the other extreme (which served as a stand).

The body may have incised decoration. Surfaces are usually slipped and well-polished, and may range from dark brown-black to brown to brownish red in color. Late Classic Period.

E. Incense Burners

1. Ladle Censers

This category groups together a variety of different spoon- or ladle-shaped incense burners. These have a handle (which may be a hollow tube or a flattened loop) which supports the ''spoon'' or ''ladle'' that actually held the embers over which incense was sprinkled. The ladle portion may have holes perforated to facilitate the circulation of air, and in the taller, more cup-like versions these holes may take the form of crosses or step frets (these are the so-called ''Mixteca-Puebla'' style censers). Animal heads, claws, or other effigies may be added to end of the handle.

2. Three-Pronged Censers

Standing cylinders with three vertical prongs at the top and two long vertical flanges on the sides. Effigy faces may be added to the vessel bodies (bats have been noted). Post-fire paint added in red, orange, and white. Late Preclassic and Early Classic Periods (Sharer 1978).

3. Lolotique Spiked Censers

The bowl-shaped censer body is supported by a tall pedestal base with perforations in the form of two large squares or circles, or slits. Short spikes cover the base and body. May retain remnants of post-fire red or white paint. Late Classic Period (Andrews 1978).

4. Las Lajas Spiked Censers

Large hourglass-shaped censer covered by short spikes. Incised or modeled decoration may be found on the everted rims found at top and bottom. An internal shelf may be present to hold the large clay dish that supported the embers. Early Postclassic Period (Fowler 1981).

5. San Andrés Stone Censers

Squat barrel-shaped censers of hard volcanic stone with columns of spikes on part of the exterior. The upper part of these censers have a dish-like depression to contain embers. Late Classic Period.

6. Large Effigy Censers

Different varieties of censers whose common traits are their relatively large size and the prominent presence of elaborate effigies covering much or all of the censer body. In extreme cases, the censer is entirely concealed within a virtual ceramic sculpture. As an alternative to a single large effigy, some present several figures on a single censer, or a single element (like a head) repeated several times. Recorded effigies have included: The god Tlaloc (identifiable by a large ring around each eye), an individual with bulbous protruding eyes, the god Xipe Totec (appearing as an individual wearing a flayed human skin), jaguars, monkeys, iguanas, large saurians (so-called Earth Monsters), GIII (a manifestation of the Sun god identifiable by a twisted cord extending vertically between the eyes and catfish-like barbels curling from the sides of the mouth), and others. Mostly Late Classic and Postclassic Periods.

7. Cotzumalhuapa Goblet Censers

Large goblet shaped vessel forms (essentially a large bowl with walls that begin as vertical and midway to the rim moderately flare outward, with a pedestal base), usually with signs of burning on the interior base. These censers may be unadorned, or may have two or three hollow head effigies rising directly from the rim, or they may have many small effigy heads attached in a row around the vessel just below its rim (monkey and iguana heads have been documented). Lids, when present, may appear as inverted bowls, with or without an effigy figure on top (one example has a large seated monkey). Late Classic Period.

F. Mushroom Effigies

Though some regard these as phallic effigies, most agree that mushrooms are represented. Two varieties are presented here.

1. Ceramic Mushroom Effigies

Tall hollow bases rise from a flaring base and taper upwards to support the mushroom ''cap''. The body may be plain or may carry red paint and fine incisions (usually in the form of rows of triangles). Probably Late Preclassic and Early Classic Periods.

2. Stone Mushroom Effigies

Usually made of fine-grained volcanic stone. The shaft of the mushroom rises from a base that may be cylindrical or square, and occasionally has short supports. Near the ''cap'' may often be found two raised bands representing the point from which the cap separates from its stem as it opens. Late Preclassic and Early Classic Periods.

G. Stone Sculpture

1. Preclassic Animal Head Sculptures

Monumental sculptures in volcanic stone representing very stylized animal heads (Demarest 1986). These have usually been interpreted as jaguar heads, and, thus, are commonly called Jaguar Heads, but reptilian elements may also be present. These were apparently architectural elements associated with Late Preclassic Period pyramids.

2. Cotzumalhuapa Sculpture

Monumental sculptures in volcanic stone in the Cotzumalhuapa style (*see* Lee A. Parsons, ''Bilbao, Guatemala'' (Vol. 1) in *Publications in Anthropology* 11, Milwaukee Public Museum, Milwaukee, Wisconsin, United States (1967) (hereinafter, referred to as ''Parsons 1967''); Lee A. Parsons, ''Bilbao, Guatemala'' (Vol. 2) in *Publications in Anthropology* 12, Milwaukee Public Museum, Milwaukee, Wisconsin, United States (1969) (hereinafter, referred to as ''Parsons 1969'')). Themes known from El Salvador include: A snake emerging from the ground, a skeletal figure with a hat resembling a derby, a coiled snake, and a disk with a jaguar face. Some of these are made from two stones which connect by means of a hidden tenon. Late Classic Period.

3. Tenoned Head Sculptures

Long sculptures of volcanic stone with an animal head at one end and an undecorated tenon at the other, intended to be mounted in monumental architecture. The heads usually represent a bird or reptile. Late Classic Period.

4. Balsamo Sculpture

These portable sculptures are usually made of vesicular volcanic stone and represent a human form in a squatting position. The vertebrae are usually indicated as a notched ridge on the individual's back. Although this form predominates, a grasshopper sculpture is also documented. Postclassic Period.

5. Yugos

''U''-shaped ballgame yugos (yokes) made of dense volcanic stone. Very rare examples may carry carved decoration. Late Classic Period.

6. Hachas

Thin ballgame hachas usually representing animal or human heads (a variety of other designs are also found, such as, a coiled snake and a skull). Made of fine-grained volcanic stone. Some examples have iron pyrite ''eyes'' and traces of red paint. Late Classic Period.

7. Effigy Metates

Metates with a thin and slightly curving body, with an animal head at one end. A tail may be present at the

other end. These are usually supported by three tall supports. Made of dense volcanic stone. Late Classic and Early Postclassic Periods.

H. Small Stone Artifacts

1. Jade or Similar Greenstone Artifacts

Lustrous and hard green-colored stone crafted into: Beads (spherical, globular, tubular, or discoidal), pendants (plain or with human or animal effigies, including so called ''axe gods'' and canine tooth effigies), plaques (or pectorals) with elaborate designs, masks, mosaics, earspools, animal or human effigies (heads or full figure), or schematic squatting human forms (similar to examples from the El Cajón area of Honduras).

2. Eccentric Chipped Stone

Flint, chert, or obsidian flaked into eccentric forms. These may include: A zigzag lance point form, a disc with three prongs or spike on one side, and elaborate large effigy eccentrics apparently meant to serve as scepters (similar to those found in caches at Copán, Quiriguá, and other sites). Late Classic Period.

3. Obsidian Artifacts in General

Prismatic blades, bifacial artifacts (lance points, arrow points, ''knives''), cores, and other objects made from obsidian (a black colored volcanic glass).

4. Pyrite Mosaic ''Mirrors''

A mosaic of carefully fitted plaques of iron pyrite placed on a thin disc-shaped backing made of stone or clay that may have designs on one side. When new, the pyrite reflected light brilliantly, but archaeological specimens have often lost their shine due to oxidation (the pyrite may convert to a brownish black crust). Late Classic and perhaps other periods.

5. Paint Pallets

Small artifacts of vesicular volcanic stone with a dish-shaped or squared depression on one surface. Some pallets are simple, being essentially natural cobbles of a flattened oblong shape with the depression worked on one surface, or sometimes two depressions on opposing surfaces. Others are elaborately carved and may include four supports and animal or human head effigies. Traces of red pigment have been found on some pallets. Late Classic and possibly other periods.

6. Translucent Stone Bowls

Thin bowls carved from light colored translucent stone (which in different cases has been labeled as marble, alabaster, and onyx). At least some of these may be ancient imports from the territory of Honduras. Late Classic Period.

7. Barkbeaters

Tabular dense stone artifacts with numerous longitudinal parallel incisions worked on one or both broad faces. On one variety (Classic and Postclassic Periods), three of the four narrow sides have a broad groove meant to receive a very pliable stick wound around it as a handle. The other variety considered here has an integral stone handle (Late Preclassic).

8. Celts

These were originally mounted on wood handles for use as hatchets or adzes. Made of very dense, fine-grained stone and are often highly polished near the bit and sometimes over the entire body. Some examples are made of jade or stone resembling jade.

I. Metal Artifacts

1. Copper Celts

Mounted on wooden handles for use as hatchets or adzes. Long copper celts with a rectangular cross section. May have a dark patina. Postclassic Period.

2. Copper Rings

Copper finger rings made with the lost wax technique. Documented examples include filigree details or effigy heads. Terminal Classic and Postclassic Periods.

3. Copper Bells

Copper bells, plain or with effigies, usually made by the lost wax technique. Postclassic Period.

4. Tumbaga Artifacts

Tumbaga is an alloy of copper and gold. Artifacts made of Tumbaga may present a mottled surface looking golden in parts. Documented Tumbaga artifacts from El Salvador include small animal figurines made by the lost wax technique, and a small hammered sheet mask with eyes and mouth cutouts. Late Classic Period.

II. Ecclesiastical Ethnological Material

Ethnological material covered by the MOU includes ecclesiastical material from the Colonial period through the first half of the twentieth century ranging in date from approximately A.D. 1525 to 1950 that was made by artisans and used for religious purposes. Salvadoran artisans created paintings, sculptures, furniture, metalwork, textiles, and craftwork for religious use in churches and cofradias, or ecclesiastical lay organizations, until the mid-twentieth century. This ethnological material was not mass-produced or industrially produced, and most works were anonymous. Examples of ethnological material covered by the MOU include, but are not limited to, the following objects:

A. Paintings

Paintings depicting figures, narratives, and events, relating to ecclesiastical themes, usually done in oil on wood, metal, walls, or canvas (linen, jute, or cotton).

B. Sculptures

Sculptural images of scenes or figures, carved in wood and usually painted, relating to ecclesiastical themes, including Christ, the Virgin Mary, saints, Anima Sola (souls in purgatory), and other figures.

1. Relief Sculptures

Low-relief plaques, often with polychrome painting, relating to ecclesiastical themes.

2. Sculpted Figures

Wood carvings of figures relating to ecclesiastical themes. Figures are decorated with polychrome painting, sometimes using the *estofado* technique. Hands and faces may be more finely carved than the torso. Eyelashes, eyes, and hair may be added. Clothing might be sculpted and painted. In some cases, the torso consists of a simple wood frame covered in fabric clothing. Figures may have articulated arms, and sometimes legs, so they can be posed to represent various religious scenes. Sculpted figures may be life-sized or miniaturized. Some figures have metal accessories, such as, halos, aureoles, and staves.

C. Furniture

Furniture used for ecclesiastical purposes, usually made from wood with glass, metal, and/or textiles attached.

1. Altarpieces or Retablos

Elaborate ornamental structures placed behind the altar, including attached paintings, sculptures, and other religious objects.

2. Reliquaries and Coffins

Containers made from wood, glass, and/or metal that hold and exhibit sacred objects or human remains.

3. Church Furnishings

Furnishings used for liturgical rites, including pulpits, tabernacles, lecterns, confessionals, pews, choir stalls, chancels, baldachins, and palanquins.

4. Processional Furnishings

Litters, canopies, coffins, cases, crosses, banners, and cofradia insignias carried in processions and made of wood, glass, and/or textiles.

D. Metalwork

Ritual objects for ceremonial ecclesiastical use made of gold, silver, and/or other metals, such as, monstrances, lecterns, chalices, censers, candlesticks, crucifixes, crosses, decorative plaques, tabernacles, processional banners, church bells, and cofradia insignias; and objects used to dress sculptures, including, among others, crowns, halos, and aureoles.

E. Textiles

Textiles used to perform religious services made from cotton or silk that may be embroidered with metallic and/or silk thread, brocades, prints, lace, fabrics, braids, and/or bobbin lace.

1. Religious Vestments

Garments worn by priests and/or other ecclesiastics, including cloaks, tunics, surplices, chasubles, dalmatics, albs, amices, stoles, maniples, cinctures, rochets, miters, bonnets, and humeral veils.

2. Garments To Dress Sculptures

Life-sized or miniaturized garments, including tunics, robes, dresses, jackets, capes, stoles, veils, belts, and embroidered cloths.

3. Coverings and Hangings

Altar cloths, towels, and tabernacle veils used for religious services.

F. Documents and Manuscripts

Original handwritten texts or printed texts of limited circulation, primarily on paper, parchment, or vellum, including religious texts, hymnals, and church records. Documents may contain wax, clay, or ink seals or stamps denoting an ecclesiastical institution. Documents are generally written in Spanish, but may include words from indigenous languages, such as, Nawat, Lenca, or Mayan languages.

Inapplicability of Notice and Delayed Effective Date

This amendment involves a foreign affairs function of the United States and is, therefore, being made without notice or public procedure (5 U.S.C. 553(a)(1)). For the same reason, a delayed effective date is not required under 5 U.S.C. 553(d)(3).

Regulatory Flexibility Act

Because no notice of proposed rulemaking is required, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply.

Executive Orders 12866 and 13771

CBP has determined that this document is not a regulation or rule subject to the provisions of Executive Order 12866 or Executive Order 13771 because it pertains to a foreign affairs function of the United States, as described above, and therefore is specifically exempted by section 3(d)(2) of Executive Order 12866 and section 4(a) of Executive Order 13771.

Signing Authority

This regulation is being issued in accordance with 19 CFR 0.1(a)(1) pertaining to the Secretary of the Treasury's authority (or that of his/her delegate) to approve regulations related to customs revenue functions.

List of Subjects in 19 CFR Part 12

Cultural property, Customs duties and inspection, Imports, Prohibited merchandise, Reporting and recordkeeping requirements.

Amendment to CBP Regulations

For the reasons set forth above, part 12 of Title 19 of the Code of Federal Regulations (19 CFR part 12), is amended as set forth below:

PART 12—SPECIAL CLASSES OF MERCHANDISE

■ 1. The general authority citation for part 12 and the specific authority for § 12.104g continue to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States (HTSUS)), 1624;

* * * * *

Sections 12.104 through 12.104i also issued under 19 U.S.C. 2612;

* * * * *

■ 2. In § 12.104g, paragraph (a), the entry for El Salvador in the table is revised to read as follows:

§ 12.104g Specific items or categories designated by agreements or emergency actions.

(a) * * *

State party	Cultural property	Decision No.
*	* * * * *	*
El Salvador	Archaeological material representing El Salvador's Pre-Hispanic cultures ranging in date from approximately 8000 B.C. through A.D. 1550 and ecclesiastical ethnological material from the Colonial period through the first half of the twentieth century ranging in date from approximately A.D. 1525 to 1950.	CBP Dec. 20–04.
*	* * * * *	*

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Dated: March 6, 2020.

Mark A. Morgan

Acting Commissioner, U.S. Customs and Border Protection.

Approved:

Timothy E. Skud,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 2020–05694 Filed 3–16–20; 11:15 am]

BILLING CODE 9111–14–P

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

29 CFR Part 1601

RIN 3046–AB17

2020 Adjustment of the Penalty for Violation of Notice Posting Requirements

AGENCY: Equal Employment Opportunity Commission.

ACTION: Final rule.

SUMMARY: In accordance with the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, which further amended the Federal Civil Penalties Inflation Adjustment Act of 1990, this final rule adjusts for inflation the civil monetary penalty for violation of the notice-posting requirements in Title VII of the Civil Rights Act of 1964, the Americans with Disabilities Act, and the Genetic Information Non-Discrimination Act.

DATES: This final rule is effective March 18, 2020.

FOR FURTHER INFORMATION CONTACT: Kathleen Oram, Assistant Legal Counsel, (202) 663–4681, or Savannah Marion Felton, Senior Attorney, (202) 663–4909, Office of Legal Counsel, 131 M St. NE, Washington, DC 20507. Requests for this notice in an alternative format should be made to the Office of Communications and Legislative Affairs at (202) 663–4191 (voice) or 1–800–669–6820 (TTY), or to the Publications Information Center at 1–800–669–3362 (toll free).

SUPPLEMENTARY INFORMATION:

I. Background

Under section 711 of the Civil Rights Act of 1964 (Title VII), which is incorporated by reference in section 105 of the Americans with Disabilities Act (ADA) and section 207 of the Genetic Information Non-Discrimination Act (GINA), and 29 CFR 1601.30(a), every employer, employment agency, labor organization, and joint labor-management committee controlling an apprenticeship or other training program covered by Title VII, ADA, or GINA must post notices describing the pertinent provisions of Title VII, ADA, or GINA. Such notices must be posted in prominent and accessible places where notices to employees, applicants, and members are customarily maintained. On average, the EEOC issues fewer than 60 posting notice violations annually.

The Equal Employment Opportunity Commission (EEOC or Commission) first adjusted the civil monetary penalty for violations of the notice posting requirements in 1997 pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990 (FCPIA Act), 28 U.S.C. 2461 note, as amended by the Debt Collection Improvement Act of 1996 (DCIA), Public Law 104–134, Sec. 31001(s)(1), 110 Stat. 1373. A final rule was published in the **Federal Register** on May 16, 1997, at 62 FR 26934, which raised the maximum penalty per violation from $100 to $110. The EEOC's second adjustment, made pursuant to the FCPIA Act, as amended by the DCIA, was published in the **Federal Register** on March 19, 2014, at 79 FR 15220 and raised the maximum penalty per violation from $110 to $210.

The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (2015 Act), Public Law 114–74, Sec. 701(b), 129 Stat. 599, further amended the FCPIA Act, to require each federal agency, not later than July 1, 2016, and not later than January 15 of every year thereafter, to issue regulations adjusting for inflation the maximum civil penalty that may be imposed pursuant to each agency's statutes. The EEOC's initial adjustment made pursuant to the 2015 Act was published in the **Federal Register** on June 2, 2016, at 81 FR 35269 and raised the maximum penalty per violation from $210 to $525. The EEOC's second adjustment made pursuant to the 2015 Act was published in the **Federal Register** on January 31, 2017, at 82 FR 8812 and raised the maximum penalty per violation from $525 to $534. EEOC's third adjustment made pursuant to the 2015 Act was published in the **Federal Register** on January 18, 2018 at 83 FR 2537 and raised the maximum penalty per violation from $534 to $545. EEOC's most recent adjustment made pursuant to the 2015 Act was published in the **Federal Register** March 21, 2019 at 84 FR 10410 and raised the maximum penalty per violation from $545 to $559.

The purpose of the annual adjustment for inflation is to maintain the remedial impact of civil monetary penalties and promote compliance with the law. These periodic adjustments to the penalty are to be calculated pursuant to the inflation adjustment formula provided in section 5(b) of the 2015 Act and, in accordance with section 6 of the 2015 Act, the adjusted penalty will apply only to penalties assessed after the effective date of the adjustment. Generally, the periodic inflation adjustment to a civil monetary penalty under the 2015 Act will be based on the percentage change between the Consumer Price Index for all Urban Consumers (CPI–U) for the month of October preceding the date of adjustment and the prior year's October CPI–U.

II. Calculation

The adjustment set forth in this final rule was calculated by comparing the CPI–U for October 2019 with the CPI–U for October 2018, resulting in an inflation adjustment factor of 1.01764. The first step of the calculation is to multiply the inflation adjustment factor (1.01764) by the most recent civil penalty amount ($559) to calculate the inflation-adjusted penalty level ($568.86076). The second step is to round this inflation-adjusted penalty to the nearest dollar ($569). Accordingly, the Commission is now adjusting the maximum penalty per violation specified in 29 CFR 1601.30(a) from $559 to $569.

III. Regulatory Procedures

Administrative Procedure Act

The Administrative Procedure Act (APA) provides an exception to the notice and comment procedures where an agency finds good cause for dispensing with such procedures, on the basis that they are impracticable, unnecessary, or contrary to the public interest. The Commission finds that under 5 U.S.C. 553(b)(3)(B) good cause exists to not utilize notice of proposed rulemaking and public comment procedures for this rule because this adjustment of the civil monetary penalty is required by the 2015 Act, the formula for calculating the adjustment to the penalty is prescribed by statute, and the Commission has no discretion in determining the amount of the published adjustment. Accordingly, the Commission is issuing this revised regulation as a final rule without notice and comment.

Executive Orders 13563, 12866, and 13771

Pursuant to Executive Order 12866, the EEOC has coordinated with the Office of Management and Budget (OMB). Under section 3(f) of Executive Order 12866, the EEOC and OMB have determined that this final rule will not have an annual effect on the economy of $100 million or more, or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities. The great majority of employers and entities covered by these regulations comply with the posting requirement, and, as a result, the aggregate economic impact of these revised regulations will be minimal, affecting only those limited few who fail to post required notices in violation of the regulation and statue. This rule is not an Executive Order 13771 regulatory action because the rule is not significant under Executive Order 12866.

Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. chapter 35) (PRA) applies to rulemakings in which an agency creates a new paperwork burden on regulated entities or modifies an existing burden. This final rule contains no new information collection requirements, and therefore, will create no new paperwork burdens or modifications to existing burdens that are subject to review by the Office of Management and Budget under the PRA.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601–612) only requires a regulatory flexibility analysis when notice and comment is required by the Administrative Procedure Act or some other statute. As stated above, notice and comment is not required for this

rule. For that reason, the requirements of the Regulatory Flexibility Act do not apply.

Unfunded Mandates Reform Act of 1995

This final rule will not result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

The Congressional Review Act (CRA) requires 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. EEOC 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 the effective date of the rule. Under the CRA, 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 the CRA at 5 U.S.C. 804(2).

List of Subjects in 29 CFR Part 1601

Administrative practice and procedure.

Dated: March 9, 2020.

Janet L. Dhillon,

Chair, Equal Employment Opportunity Commission.

Accordingly, the Equal Employment Opportunity Commission amends 29 CFR part 1601 as follows:

PART 1601—PROCEDURAL REGULATIONS

■ 1. The authority citation for part 1601 continues to read as follows:

Authority: 29 U.S.C. 621–634; 28 U.S.C. 2461 note; 5 U.S.C. 301; Pub. L. 99–502; 100 Stat. 3341; Secretary's Order No. 10–68; Secretary's Order No. 11–68; sec. 2 Reorg. Plan No. 1 of 1978, 43 FR 19807; Executive Order 12067, 43 FR 28967.

■ 2. Section 1601.30 is amended by revising paragraph (b) to read as follows:

§ 1601.30 Notices to be posted.

* * * * *

(b) Section 711(b) of Title VII and the Federal Civil Penalties Inflation Adjustment Act, as amended, make failure to comply with this section punishable by a fine of not more than $569 for each separate offense.

[FR Doc. 2020–05225 Filed 3–17–20; 8:45 am]

BILLING CODE 6570–01–P

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Parts 4022 and 4044

Allocation of Assets in Single-Employer Plans; Benefits Payable in Terminated Single-Employer Plans; Interest Assumptions for Valuing and Paying Benefits

AGENCY: Pension Benefit Guaranty Corporation (PBGC).

ACTION: Final rule.

SUMMARY: This final rule amends the Pension Benefit Guaranty Corporation's regulations on Benefits Payable in Terminated Single-Employer Plans and Allocation of Assets in Single-Employer Plans to prescribe certain interest assumptions under the benefit payments regulation for plans with valuation dates in April 2020 and interest assumptions under the asset allocation regulation for plans with valuation dates in the second quarter of 2020. These interest assumptions are used for valuing benefits and paying certain benefits under terminating single-employer plans covered by the pension insurance system administered by PBGC.

DATES: Effective April 1, 2020.

FOR FURTHER INFORMATION CONTACT: Gregory Katz (*katz.gregory@pbgc.gov*), Attorney, Regulatory Affairs Division, Pension Benefit Guaranty Corporation, 1200 K Street NW, Washington, DC 20005, 202–326–4400, ext. 3829. (TTY users may call the Federal relay service toll free at 1–800–877–8339 and ask to be connected to 202–326–4400, ext. 3829.)

SUPPLEMENTARY INFORMATION: PBGC's regulations on Allocation of Assets in Single-Employer Plans (29 CFR part 4044) and Benefits Payable in Terminated Single-Employer Plans (29 CFR part 4022) prescribe actuarial assumptions—including interest assumptions—for valuing and paying plan benefits under terminating single-employer plans covered by title IV of the Employee Retirement Income Security Act of 1974 (ERISA). The interest assumptions in the regulations are also published on PBGC's website (*https://www.pbgc.gov*).

Lump Sum Interest Assumption

PBGC uses the interest assumptions in appendix B to part 4022 (''Lump Sum Interest Rates for PBGC Payments'') to determine whether a benefit is payable as a lump sum and to determine the amount to pay as a lump sum. Because some private-sector pension plans use these interest rates to determine lump sum amounts payable to plan participants (if the resulting lump sum is larger than the amount required under section 417(e)(3) of the Internal Revenue Code and section 205(g)(3) of ERISA), these rates are also provided in appendix C to part 4022 (''Lump Sum Interest Rates for Private-Sector Payments'').

This final rule updates appendices B and C of the benefit payments regulation to provide the rates for April 2020 measurement dates.

The April 2020 lump sum interest assumptions will be 0.00 percent for the period during which a benefit is (or is assumed to be) in pay status and 4.00 percent during any years preceding the benefit's placement in pay status. In comparison with the interest assumptions in effect for March 2020, these assumptions represent no change in the immediate rate and are otherwise unchanged.

Valuation/Asset Allocation Interest Assumptions

PBGC uses the interest assumptions in appendix B to part 4044 (''Interest Rates Used to Value Benefits'') to value benefits for allocation purposes under section 4044 of ERISA, and some private-sector pension plans use them to determine benefit liabilities reportable under section 4044 of ERISA and for other purposes. The second quarter 2020 interest assumptions will be 2.11 percent for the first 20 years following the valuation date and 1.92 percent thereafter. In comparison with the interest assumptions in effect for the first quarter of 2020, these interest assumptions represent a decrease of 5 years in the select period (the period during which the select rate (the initial rate) applies), a decrease of 0.01 percent in the select rate, and a decrease of 0.34 percent in the ultimate rate (the final rate).

Need for Immediate Guidance

PBGC updates appendix B of the asset allocation regulation each quarter and appendices B and C of the benefit payments regulation each month. PBGC has determined that notice and public comment on this amendment are impracticable and contrary to the public interest. This finding is based on the need to issue new interest assumptions promptly so that they are available to value benefits and, for plans that rely on our publication of them each month or

each quarter, to calculate lump sum benefit amounts.

Because of the need to provide immediate guidance for the valuation and payment of benefits under plans with valuation dates during April 2020, PBGC finds that good cause exists for making the assumptions set forth in this amendment effective less than 30 days after publication.

PBGC has determined that this action is not a ''significant regulatory action'' under the criteria set forth in Executive Order 12866.

Because no general notice of proposed rulemaking is required for this amendment, the Regulatory Flexibility Act of 1980 does not apply. See 5 U.S.C. 601(2).

List of Subjects

29 CFR Part 4022

Employee benefit plans, Pension insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 4044

Employee benefit plans, Pension insurance, Pensions.

In consideration of the foregoing, 29 CFR parts 4022 and 4044 are amended as follows:

PART 4022—BENEFITS PAYABLE IN TERMINATED SINGLE-EMPLOYER PLANS

■ 1. The authority citation for part 4022 continues to read as follows:

Authority: 29 U.S.C. 1302, 1322, 1322b, 1341(c)(3)(D), and 1344.

■ 2. In appendix B to part 4022, Rate Set 318 is added at the end of the table to read as follows:

Appendix B to Part 4022—Lump Sum Interest Rates For PBGC Payments

* * * * *

Rate set	For plans with a valuation date		Immediate annuity rate (percent)	Deferred annuities (percent)				
	On or after	Before		i_1	i_2	i_3	n_1	n_2
*	*		*	*	*	*	*	
318	4–1–20	5–1–20	0.00	4.00	4.00	4.00	7	8

■ 3. In appendix C to part 4022, Rate Set 318 is added at the end of the table to read as follows:

Appendix C to Part 4022—Lump Sum Interest Rates For Private-Sector Payments

* * * * *

Rate set	For plans with a valuation date		Immediate annuity rate (percent)	Deferred annuities (percent)				
	On or after	Before		i_1	i_2	i_3	n_1	n_2
		*	* *	*	*	* *		
318	4–1–20	5–1–20	0.00	4.00	4.00	4.00	7	8

PART 4044 — ALLOCATION OF ASSETS IN SINGLE–EMPLOYER PLANS

■ 4. The authority citation for part 4044 continues to read as follows:

Authority: 29 U.S.C. 1301(a), 1302(b)(3), 1341, 1344, 1362.

■ 5. In appendix B to part 4044, an entry for ''April—June 2020'' is added at the end of the table to read as follows:

Appendix B to Part 4044—Interest Rates Used to Value Benefits

* * * * *

For valuation dates occurring in the month—	The values of i_t are:					
	i_t	for t =	i_t	for t =	i_t	for t =
*	*	*	*	*	*	*
April–June 2020	0.0211	1–20	0.0192	>20	N/A	N/A

Issued in Washington, DC, by:

Hilary Duke,

Assistant General Counsel, Pension Benefit Guaranty Corporation.

[FR Doc. 2020–05545 Filed 3–17–20; 8:45 am]

BILLING CODE 7709–02–P

DEPARTMENT OF THE TREASURY

31 CFR Part 150

RIN 1505–AC59

Assessment of Fees on Certain Bank Holding Companies and Nonbank Financial Companies Supervised by the Federal Reserve Board To Cover the Expenses of the Financial Research Fund

AGENCY: Departmental Offices, Department of the Treasury.

ACTION: Final rule.

SUMMARY: The Department of the Treasury (''Treasury'') is issuing this final rule to implement section 401 of the Economic Growth, Regulatory Relief, and Consumer Protection Act (the ''Economic Growth Act''), which amends section 155 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (the ''Dodd-Frank Act''). As amended, section 155 requires the Secretary of the Treasury to establish, by regulation, an assessment schedule applicable to bank holding companies with total consolidated assets of $250 billion or greater and nonbank financial companies supervised by the Board of Governors of the Federal Reserve System (''the Board''), to collect assessments equal to the total expenses of the Office of Financial Research (the ''OFR''). The final rule also simplifies the method for determining the amount of total assessable assets for foreign banking organizations, which is made possible by a new regulatory data source. This rule finalizes a November 4, 2019 proposed rule without change.

DATES: This rule is effective April 17, 2020.

FOR FURTHER INFORMATION CONTACT: John Zitko, Senior Counsel, OFR, (202) 927–8372.

SUPPLEMENTARY INFORMATION:

I. Background

Section 155(d) of the Dodd-Frank Act directs the Secretary of the Treasury to establish, by regulation, and with the approval of the Financial Stability Oversight Council (the ''Council''), an assessment schedule to collect assessments from certain companies equal to the total expenses of the OFR. On May 21, 2012, Treasury published a final regulation implementing section 155(d) in the **Federal Register**, codified at 31 CFR part 150 (the ''Original Rule''). Before the enactment of the Economic Growth Act, pursuant to section 155(d) and the implementing regulation, Treasury collected assessments from bank holding companies with total consolidated assets of $50,000,000,000 or greater and nonbank financial companies supervised by the Board.

On May 24, 2018, the Economic Growth Act was signed into law. Section 401(c)(1) of the Economic Growth Act replaced the $50 billion reference in section 155(d) of the Dodd-Frank Act with $250 billion. In addition, section 401(f) of the Economic Growth Act required any bank holding company identified as a global systemically important bank holding company (''G–SIB'') pursuant to 12 CFR 217.402 to be considered a bank holding company with total consolidated assets equal to or greater than $250 billion for purposes of section 155(d) of the Dodd-Frank Act. As a result of this statutory amendment, bank holding companies with less than $250 billion in total consolidated assets that are not G–SIBs are not to be assessed under Dodd-Frank Act section 155(d).

The Economic Growth Act sets forth two different effective dates. For bank holding companies with total consolidated assets of less than $100 billion, it became effective on May 24, 2018 (the date of enactment). For bank holding companies with total consolidated assets of $100 billion or more and for G–SIBs, the effective date was November 24, 2019 (18 months after the date of enactment). This final rule, in part, implements section 401.

Under section 118 of the Dodd-Frank Act, the expenses of the Council are treated as expenses of, and are paid by, the OFR. In addition, under section 210 of the Dodd-Frank Act, certain implementation expenses of the Federal Deposit Insurance Corporation (''FDIC'') associated with the FDIC's orderly liquidation authority are treated as expenses of the Council,[1] and the FDIC is directed to periodically submit requests for reimbursement to the Chairperson of the Council. The total expenses for the OFR therefore include the combined expenses of the OFR and the Council and certain expenses of the FDIC. All of these expenses are paid out of the Financial Research Fund (the ''FRF''), a fund managed by Treasury.

The Council was established by the Dodd-Frank Act to identify risks to U.S. financial stability, promote market discipline, and respond to emerging threats to the stability of the U.S. financial system. The Council is chaired by the Secretary of the Treasury, and its 15 members include all of the federal financial regulators, an independent member with insurance expertise appointed by the President, and state financial regulators.

The OFR was established within Treasury by the Dodd-Frank Act to support the Council and its member agencies. Among the OFR's key duties are:

- Collecting data on behalf of the Council and providing such data to the Council and member agencies;
- Standardizing the types and formats of data reported and collected;
- Performing research;
- Developing tools for risk measurement and monitoring; and
- Reporting to Congress and the public on the OFR's assessment of significant financial market developments and potential emerging threats to U.S. financial stability.

II. The Proposed and Final Rule

Treasury issued a proposed rule on November 4, 2019, to implement the changes to the FRF assessments required by the Economic Growth Act.[2] The proposed rule also included certain other amendments to 31 CFR part 150 to simplify the method for determining the amount of total assessable assets for certain entities, to remove outdated references to the initial assessment period (which concluded in 2013), and to make other non-substantive changes to add clarifying or remove redundant language.

Treasury received no public comments on the proposed rule. Accordingly, Treasury is issuing this final rule as proposed. Following is a description of the changes the final rule makes to the Original Rule.

a. Determination of Assessed Companies

To impose assessments under section 155 of the Dodd-Frank Act, Treasury must identify companies that are subject to the assessment. As described in the Original Rule and below, Treasury works closely with the Board to determine the population of assessed companies.

The original text of Dodd-Frank Act section 155(d) required assessments to be collected from bank holding companies with total consolidated assets of $50 billion or greater and nonbank financial companies supervised by the Board. The Economic Growth Act raised the asset threshold

[1] Under Section 210(n)(10)(C) of the Dodd-Frank Act the term implementation expenses ''(i) means costs incurred by [the FDIC] beginning on the date of enactment of this Act, as part of its efforts to implement [Title II] that do not relate to a particular covered financial company; and (ii) includes the costs incurred in connection with the development of policies, procedures, rules, and regulations and other planning activities of the [FDIC] consistent with carrying out [Title II].''

[2] 84 FR 59320 (November 4, 2019).

for bank holding companies to $250 billion and also stated that a bank holding company, regardless of asset size, that has been identified as a G–SIB under § 217.402 of title 12, Code of Federal Regulations, shall be considered a bank holding company with total consolidated assets equal to or greater than $250 billion for purposes of section 155(d) of the Dodd-Frank Act.

Accordingly, the final rule changes the definitions of ''Assessed Company'' and ''Total Assessable Assets'' in 12 CFR 150.2, and deletes the reference to foreign banking organizations with less than $50 billion in 12 CFR 150.5.

b. Determination of Total Assessable Assets

i. Foreign Banking Organizations

At the time of adoption of the Original Rule, there was no single regulatory reporting form that provided a foreign banking organization's total assets of combined U.S. operations, including its U.S. branches, agencies, and subsidiaries. The preamble to the Original Rule specifically noted the possibility that reporting requirements for foreign banking organizations would change over time and that the list of reports would need to be adjusted.[3] To allow for the possibility of these changes, the Original Rule did not include a list of specific reference reports for foreign banking organizations, in contrast to U.S. bank holding companies. It was noted that calculating banking organizations' total assets of combined U.S. operations based on multiple reports could result in double-counting.[4] The preamble to the Original Rule stated that Treasury would make every effort to avoid double-counting, consulting with the Board and the affected firms as necessary, and that any questions could be addressed through the appeals process.[5]

After the adoption of the Original Rule, the Board modified its form FR Y–7Q by adding a line item for reporting the total combined assets of a foreign banking organization's U.S. operations. Line item 6 of part 1A of FR Y–7Q now requires reporting of the total combined assets of a top-tier foreign banking organization's U.S.-domiciled affiliates, branches, and agencies, excluding intercompany balances and intercompany transactions between those entities to the extent such items are not already eliminated in consolidation.[6] Accordingly, to simplify the method for determining the amount of total assessable assets for foreign banking organizations and to adopt an approach for foreign banking organizations comparable to the approach under the Original Rule for U.S. bank holding companies, the final rule includes changes to the definition of ''total assessable assets'' by specifying that the calculation of a foreign banking organization's total assessable assets shall be based on the data reported in the FR Y–7Q.

ii. Timing of Determination Dates, Billing, and Collection

Under the Original Rule, assessments were semiannual. On the specified determination date before each assessment period, Treasury determined the pool of assessed companies, which received confirmation statements. After any appeals, assessments were debited from assessed companies' accounts on the assessment payment date.

The Original Rule generally used a period of four calendar quarters to measure the total assessable assets of both U.S. and foreign entities for assessments. Thus, for the assessment period with a November 30 determination date, total assessable assets were based on the company's regulatory filings for the fourth quarter of the previous calendar year and the first three quarters of the same calendar year. For the assessment period with a May 31 determination date, total assessable assets were based on the company's filings for the last three quarters of the previous year and the first quarter of the same calendar year.

Both the Federal Reserve's form FR Y–9C, which the Original Rule required to be used to determine total assessable assets of U.S. bank holding companies, and the FR Y–7Q, which the final rule incorporates to determine the total assessable assets of foreign banking organizations, are quarterly reports. Their filing deadlines, however, are asynchronous, as the FR Y–9C generally must be filed within 40 calendar days after each calendar quarter,[7] and the FR Y–7Q generally must be filed within 90 calendar days after the quarter ends. The timing of updated reports therefore varies. For example, on the determination date of May 31 under the Original Rule, the FR Y–9C reports were already available for Q1 of the same year, but Q1 reports on FR Y–7Q were not due until approximately one month later (June 29).

To enable consistency in the timing of determining assessable assets for U.S. and foreign entities, the final rule moves each of the two semiannual determination dates one month earlier. Accordingly, the first determination date in each calendar year will be April 30 instead of May 31 as under the Original Rule, and the second determination date will be October 31, instead of November 30 as under the Original Rule. This change enables each assessment to be based on companies' filings for the last two calendar quarters of the previous year and the first two quarters of the current calendar year for assessment periods with an October 31 determination date, and all four quarters of the previous calendar year for assessment periods with an April 30 determination date.

Consistent with Treasury's process under the Original Rule, the final rule provides that before each assessment period, after determining the pool of assessed companies and publishing an assessment fee rate, Treasury will calculate the assessment fee for each assessed company, send an electronic billing notification to each assessed company, and, on the assessment payment date, initiate a direct debit to each company's account through *www.pay.gov* to collect the assessments. The final rule retains the process under the Original Rule, with one additional month added to the beginning of each cycle, as described above, while keeping the dates under the Original Rule for the notice of fees, billing, and payment. In order to provide additional clarity as to when redetermination requests must be received from companies wishing to appeal their status as an assessed company or the total assessable assets that the Department has determined will be used for calculating the company's assessment, the final rule amends the reference to such date in 12 CFR 150.6(b) from ''one month'' to ''30 calendar days.''

The table below shows approximate dates of the assessment billing and collection process under the final rule:

[3] 77 FR 29890 (May 21, 2012).

[4] 77 FR 29888–89 (May 21, 2012).

[5] 77 FR 29889 (May 21, 2012).

[6] See Federal Reserve, The Capital and Asset Report for Foreign Banking Organizations—FR Y–7Q, available at *https://www.federalreserve.gov/reportforms/forms/FR_Y-7Q20190331_f.pdf.*

[7] Reports as of December 31 are due 45 calendar days later.

Assessment period	Determination date	Confirmation statement date	Redetermination request deadline	Initial response to redetermination request	Publication of notice of fees*	Billing date	Payment date
1st semiannual assessment period. (April—September)	October 31 ...	November 15 (or next business day).	30 calendar days from date of Confirmation Statement.	21 calendar days from receipt of Redetermination Request.	February 15 (or next business day).	March 1 (or prior business day).	March 15 (or next business day).
2nd semiannual assessment period. (October—March) ..	April 30	May 15 (or next business day).	30 calendar days from date of Confirmation Statement.	21 calendar days from receipt of Redetermination Request.	August 15 (or next business day).	September 1 (or prior business day).	September 15 (or next business day).

*Rate published in the Notice of Fees.

The timeframe for sending confirmation statements and receiving appeals under the final remains the same as under the Original Rule. Specifically, confirmation statements will continue to be mailed no later than 15 calendar days after the determination date, and appeals by assessable companies will continue to be due one month later. In addition to promoting consistent measurements of U.S. and foreign entities, as noted above, adding a month to the beginning of the FRF assessments cycle will also afford assessed companies additional time to address appeals and make payment arrangements, and will provide Treasury additional time to calculate assessments and administer the billing process.

III. Administrative Law Matters

a. Regulatory Flexibility Act

Congress enacted the Regulatory Flexibility Act (the ''RFA'') to address concerns related to the effects of agency rules on small entities.[8] Treasury is sensitive to the impact its rules may impose on small entities. The RFA requires agencies either to provide an initial regulatory flexibility analysis with a proposed rule for which general notice of proposed rulemaking is required, or to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.[9]

Under regulations issued by the Small Business Administration, a ''small entity'' includes those firms within the ''Finance and Insurance'' sector with asset sizes that vary from $7.5 million in assets to $600 million or less in assets.[10] For purposes of the RFA, entities that are banks are considered small entities if their assets are less than or equal to $600 million.

As discussed above, under section 155 of the Dodd-Frank Act, as amended by the Economic Growth Act, only bank holding companies with more than $250 billion in total consolidated assets, G-SIBs, and nonbank financial companies supervised by the Board will be subject to assessments under the final rule. As such, the final rule will not apply to small entities and a regulatory flexibility analysis is not required.

Pursuant to the Regulatory Flexibility Act, 5 U.S.C. 605(b), it is hereby certified that this final rule will not have a significant economic impact on a substantial number of small entities.

b. Paperwork Reduction Act

We estimate that there are certain direct costs associated with complying with these rules. On a one-time basis, assessed entities are required to set up a bank account for fund transfers and to provide the required information to Treasury through an information collection form. The form includes bank account routing information and contact information for the individuals at the company who will be responsible for setting up the account and ensuring that funds are available on the billing date. We estimate that approximately 20 companies could be affected, and that completing the form and submitting it to Treasury will take approximately 15 minutes. The aggregate paperwork burden is estimated at 5.0 hours. However, all of these companies have already established an account for payments or collections to the U.S. Government pursuant to the Original Rule.

On a semiannual basis, assessed companies have the opportunity to review the confirmation statement and assessment bill. The final rule does not require the companies to conduct this review, but does permit it. We anticipate that at least some of the companies will conduct reviews, in part because the cost associated with it is very low.

The collection of information contained in the final rule has been reviewed and approved by the Office of Management and Budget (OMB) under OMB control number 1505–0245. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a valid OMB control number.

c. Regulatory Planning and Review (Executive Orders 12866 and 13563)

This final rule is not a significant regulatory action as defined in section 3(f) of Executive Order 12866 as supplemented by Executive Order 13563.

List of Subjects in 31 CFR Part 150

Bank holding companies, Financial research fund, Nonbank financial companies.

■ For the reasons set forth in the preamble, title 31, part 150, of the Code of Federal Regulations is revised to read as follows:

PART 150—FINANCIAL RESEARCH FUND

Sec.
150.1 Scope.
150.2 Definitions.
150.3 Determination of assessed companies.
150.4 Calculation of assessment basis.
150.5 Calculation of assessments.
150.6 Notice and payment of assessments.

Authority: 12 U.S.C. 5345; 31 U.S.C. 321; 12 U.S.C. 5365 *note* (Section 401(d), Pub. L. 115–174, 132 Stat. 1358; Section 401(f), Pub. L. 115–174, 132 Stat. 1359).

§ 150.1 Scope.

The assessments contained in this part are made pursuant to the authority contained in 12 U.S.C. 5345.

§ 150.2 Definitions.

As used in this part:

Assessed company means:

(1) A bank holding company that has $250 billion or more in total assessable assets; or

(2) A bank holding company, regardless of asset size, that has been identified as a global systemically important bank holding company under § 217.402 of title 12, Code of Federal Regulations; or

(3) A nonbank financial company that the Council has determined under section 113 of the Dodd-Frank Act shall be supervised by the Board.

Assessment basis means, for a given assessment period, an estimate of the total expenses that are necessary or appropriate to carry out the

[8] 5 U.S.C. 601 *et seq.*

[9] 5 U.S.C. 603(a).

[10] 13 CFR 121.201.

responsibilities of the Office of Financial Research (OFR) and the Council as set out in the Dodd-Frank Act (including an amount necessary to reimburse reasonable implementation expenses of the Corporation that shall be treated as expenses of the Council pursuant to section 210(n)(10) of the Dodd-Frank Act).

Assessment fee rate, with regard to a particular assessment period, means the rate published by the Department for the calculation of assessment fees for that period.

Assessment payment date means:

(1) For any assessment period ending on March 31 of a given calendar year, September 15 of the prior calendar year; and

(2) For any assessment period ending on September 30 of a given calendar year, March 15 of the same year.

Assessment period means:

(1) Any period of time beginning on October 1 and ending on March 31 of the following calendar year; or

(2) Any period of time beginning on April 1 and ending on September 30 of the same calendar year.

Bank holding company means:

(1) A bank holding company as defined in section 2 of the Bank Holding Company Act of 1956 (12 U.S.C. 1841); or

(2) A foreign banking organization.

Board means the Board of Governors of the Federal Reserve System.

Corporation means the Federal Deposit Insurance Corporation.

Council means the Financial Stability Oversight Council.

Department means the Department of the Treasury.

Determination date means:

(1) For any assessment period ending on March 31 of a given calendar year, April 30 of the prior calendar year; and

(2) For any assessment period ending on September 30 of a given calendar year, October 31 of the prior calendar year.

Dodd-Frank Act means the Dodd-Frank Wall Street Reform and Consumer Protection Act.

Foreign banking organization means a foreign bank or company that is treated as a bank holding company for purposes of the Bank Holding Company Act of 1956, pursuant to section 8(a) of the International Banking Act of 1978 (12 U.S.C. 3106(a)).

OFR means the Office of Financial Research established by section 152 of the Dodd-Frank Act.

Total assessable assets means:

(1) For a bank holding company other than a foreign banking organization, the average of the company's total consolidated assets for the four quarters preceding the relevant determination date, as reported on the bank holding company's four most recent Consolidated Financial Statements for Bank Holding Companies—FR Y–9C filings;

(2) For any foreign banking organization, the average of the company's total assets of combined U.S. operations for the four quarters preceding the relevant determination date, as reported on the foreign banking organization's four most recent quarterly Capital and Asset Report for Foreign Banking Organizations—FR Y–7Q filings, or, if the foreign banking organization only files such form annually, the average of the two most recent annual filings on such form; or

(3) For a nonbank financial company that the Council has determined under section 113 of the Dodd-Frank Act shall be supervised by the Board, either the average of the company's total consolidated assets for the four quarters preceding the relevant determination date, if the company is a U.S. company, or the average of the total assets of the company's combined U.S. operations for the four quarters preceding the relevant determination date, if the company is a non-U.S. company.

§ 150.3 Determination of assessed companies.

(a) The determination that a bank holding company or a nonbank financial company is an assessed company will be made by the Department.

(b) The Department will apply the following principles in determining whether a company is an assessed company:

(1) For tiered bank holding companies for which a holding company owns or controls, or is owned or controlled by, other holding companies, the assessed company shall be the top-tier, regulated holding company.

(2) In situations where more than one top-tier, regulated bank holding company has a legal authority for control of a U.S. bank, each of the top-tier regulated holding companies shall be designated as an assessed company.

(3) In situations where a company has not filed four consecutive quarters of the financial reports referenced above for the most recent quarters (or two consecutive years for annual filers of the FR Y–7Q or successor form), such as may be true for companies that recently converted to a bank holding company, the Department will use, at its discretion, other financial or annual reports filed by the company, such as Securities and Exchange Commission (SEC) filings, to determine a company's total consolidated assets.

(4) In situations where a company does not report total consolidated assets in its public reports or where a company uses a financial reporting methodology other than U.S. generally accepted accounting principles (GAAP) to report on its U.S. operations, the Department will use, at its discretion, any comparable financial information that the Department may require from the company for this determination.

(c) Any company that the Department determines is an assessed company on a given determination date will be an assessed company for the entire assessment period related to such determination date, and will be subject to the full assessment fee for that assessment period, regardless of any changes in the company's assets or other attributes that occur after the determination date.

§ 150.4 Calculation of assessment basis.

For each assessment period, the Department will calculate an assessment basis that shall be sufficient to replenish the Financial Research Fund to a level equivalent to the sum of:

(a) Budgeted operating expenses for the OFR for the applicable assessment period;

(b) Budgeted operating expenses for the Council for the applicable assessment period;

(c) Budgeted capital expenses for the OFR for the 12-month period beginning on the first day of the applicable assessment period;

(d) Budgeted capital expenses for the Council for the 12-month period beginning on the first day of the applicable assessment period; and

(e) An amount necessary to reimburse reasonable implementation expenses of the Corporation as provided under section 210(n)(10) of the Dodd-Frank Act.

§ 150.5 Calculation of assessments.

(a) For each assessed company, the Department will calculate the total assessable assets in accordance with the definition in § 150.2.

(b) The Department will allocate the assessment basis to the assessed companies in the following manner:

(1) Based on the sum of all assessed companies' total assessable assets, the Department will calculate the assessment fee rate necessary to collect the assessment basis for the applicable assessment period.

(2) The assessment payable by an assessed company for each assessment period shall be equal to the assessment fee rate for that assessment period multiplied by the total assessable assets of such assessed company.

§ 150.6 Notice and payment of assessments.

(a) No later than fifteen calendar days after the determination date, the Department will send to each assessed company a statement that:

(1) Confirms that such company has been determined by the Department to be an assessed company; and

(2) States the total assessable assets that the Department has determined will be used for calculating the company's assessment.

(b) If a company that is required to make an assessment payment for a given assessment period believes that the statement referred to in paragraph (a) of this section contains an error, the company may provide the Department with a written request for a revised statement. Such request must be received by the Department via email within 30 calendar days and must include all facts that the company requests the Department to consider. The Department will respond to all such requests within 21 calendar days of receipt thereof.

(c) No later than the 14 calendar days prior to the payment date for a given assessment period, the Department will send an electronic billing notification to each assessed company, containing the final assessment that is required to be paid by such assessed company.

(d) For the purpose of making the payments described in § 150.5, each assessed company shall designate a deposit account for direct debit by the Department through *www.pay.gov* or successor website. No later than the later of 30 days prior to the payment date for an assessment period, or April 17, 2020, each such company shall provide notice to the Department of the account designated, including all information and authorizations required by the Department for direct debit of the account. After the initial notice of the designated account, no further notice is required unless the company designates a different account for assessment debit by the Department, in which case the requirements of the preceding sentence apply.

(e) Each assessed company shall take all actions necessary to allow the Department to debit assessments from such company's designated deposit account. Each such company shall, prior to each assessment payment date, ensure that funds in an amount at least equal to the amount on the relevant electronic billing notification are available in the designated deposit account for debit by the Department. Failure to take any such action or to provide such funding of the account shall be deemed to constitute nonpayment of the assessment. The Department will cause the amount stated in the applicable electronic billing notification to be directly debited on the appropriate payment date from the deposit account so designated.

(f) In the event that, for a given assessment period, an assessed company materially misstates or misrepresents any information that is used by the Department in calculating that company's total assessable assets, the Department may at any time re-calculate the assessment payable by that company for that assessment period, and the assessed company shall take all actions necessary to allow the Department to immediately debit any additional payable amounts from such assessed company's designated deposit account.

(g) If a due date under this section falls on a date that is not a business day, the applicable date shall be the next business day.

Dated: March 6, 2020.

Kipp Kranbuhl,

Principal Deputy Assistant Secretary, Financial Markets, Department of the Treasury.

[FR Doc. 2020–05083 Filed 3–17–20; 8:45 am]

BILLING CODE 4810–25–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2020–0153]

RIN 1625–AA08

Special Local Regulation; Gulfport Grand Prix, Boca Ciego Bay, Gulfport, FL

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a special local regulation on the waters of the Boca Ciego Bay in the vicinity of Gulfport, Florida, during the Gulfport Grand Prix High Speed Boat Race. Approximately 75 boats, 14–30 feet in length, traveling at speeds in excess of 120 miles per hour are expected to participate. Additionally, it is anticipated that 100 spectator vessels will be present along the race course. The special local regulation is necessary to protect the safety of race participants, participant vessels, spectators, and the general public on navigable waters of the Gulf of Mexico during the event. The special local regulation will establish the following regulated areas: A race area where all non-participant persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within the regulated area unless authorized by the Captain of the Port St. Petersburg (COTP) or a designated representative; and a buffer zone where designated representatives may control vessel traffic as deemed necessary by the COTP St. Petersburg or a designated representative based upon prevailing weather conditions.

DATES: This rule is effective from 8 a.m. on March 27, 2020 through 6 p.m. on March 29, 2020.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2020–0153 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 Marine Science Technician First Class Michael D. Shackleford, Sector St. Petersburg Prevention Department, Coast Guard; telephone (813) 228–2191, email *Michael.D.Shackleford@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
Pub. L. Public Law
§ Section
U.S.C. United States Code
COTP Captain of the Port

II. Background Information and Regulatory History

On January 14, 2020, the Coast Guard issued a notice of proposed rulemaking (NPRM) entitled ''Special Local Regulations: Recurring Marine Events, Sector St. Petersburg'' (85 FR 2069) proposing to amend the list of recurring marine events/special local regulations occurring solely within the COTP St. Petersburg Zone. The NPRM provided for a 30 day comment period which closed on February 13, 2020. An event listed in the NPRM, titled ''Gulfport Grand Prix/Gulfport Grand Prix LLC [1]'' is scheduled to occur daily from 8 a.m. until 6 p.m. on March 27, 2020 through March 29, 2020.

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

[1] This event is listed in the NPRMs proposed regulatory text at 33 CFR 100.703, Table to § 100.703, line number 3.

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 and contrary to the public interest. There is insufficient time to finalize the NPRM referenced above before the event is scheduled to occur. Because of the potential safety hazards associated with the race, immediate action is needed to provide for the safety of the race participants, spectators, and vessels transiting the event area. Immediate action is also necessary for the protection of life and property on the navigable waters of Boca Ciego Bay in the vicinity of Gulfport, Florida, during the Gulfport Grand Prix High Speed Boat Race.

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** for the same reasons discussed above.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70041. The Captain of the Port St. Petersburg (COTP) has determined that potential hazards associated with the event pose a safety concern for event participants, spectators, and the general public in the immediate vicinity. The purpose of the rule is to provide for the safety of life on navigable waters of the United States during Gulfport Grand Prix High Speed Boat Race event.

IV. Discussion of the Rule

This rule establishes a special local regulation that will encompass certain waters of the Boca Ciega Bay in the vicinity of Gulfport, Florida. The special local regulation will be enforced daily from 8 a.m. to 6 p.m. on March 27, 2020 through March 29, 2020. The special local regulation will establish two regulated areas: (1) A race area where all persons and vessels, except those persons and vessels participating in the high speed boat races, are prohibited from entering, transiting through, anchoring in, or remaining within the regulated area without obtaining permission from the COTP St. Petersburg or a designated representative; and (2) a buffer zone where vessel traffic may be controlled as determined by the COTP St. Petersburg or a designated representative based upon prevailing weather conditions.

Persons and vessels may request authorization to enter, transit through, anchor in, or remain within the regulated area by contacting the Captain of the Port (COTP) St. Petersburg by telephone at (727) 824–7506, or a designated representative via VHF radio on channel 16. If authorization to enter, transit through, anchor in, or remain within the regulated area is granted by the COTP St. Petersburg or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the COTP St. Petersburg or a designated representative. The Coast Guard will provide notice of the regulated areas by Local Notice to Mariners, Broadcast Notice to Mariners, or by on-scene designated representatives.

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. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. 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), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on: (1) The special local regulation will be enforced for only ten hours on three days; (2) although persons and vessels may not enter, transit through, anchor in, or remain within the regulated area without authorization from the COTP St. Petersburg or a designated representative, they may operate in the surrounding area during the enforcement period; (3) persons and vessels may still enter, transit through, anchor in, or remain within the regulated area or anchor in the spectator area, during the enforcement period if authorized by the COTP St. Petersburg or a designated representative; and (4) the Coast Guard will provide advance notification of the special local regulation to the local maritime community by Local Notice to Mariners and/or Broadcast Notice to Mariners.

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 would not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section 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 contact 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 would not result in such 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 special local regulation issued in conjunction with a regatta or marine parade enforced for ten hours daily over a period of three days that will prohibit non-participant persons and vessels from entering, transiting through, remaining within, or anchoring in the regulated area. It is categorically excluded from further review under paragraph L61 in Table 3–1 of U.S. Coast Guard Environmental Planning Implementing Procedures. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact 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 100

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

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 46 U.S.C. 70041; 33 CFR 1.05–1.

■ 2. Add § 100.T07–0153 to read as follows:

§ 100.T07–0153 Special Local Regulation; Gulfport Grand Prix, Boca de Ciego; Gulfport, FL.

(a) *Location.* The following regulated areas are established as a special local regulation. All coordinates are North American Datum 1983.

(1) *Race area.* All waters of Boca de Ciego contained within the following points: 27°44′10″ N, 082°42′29″ W, thence to position 27°44′07″ N, 082°42′40″ W, thence to position 27°44′06″ N, 082°42′40″ W, thence to position 27°44′04″ N, 082°42′29″ W, thence to position 27°44′07″ N, 082°42′19″ W, thence to position 27°44′08″ N, 082°42′19″ W, thence back to the original position, 27°44′10″ N, 082°42′29″ W.

(2) *Buffer zone.* All waters of Boca de Ciego encompassed within the following points: 27°44′10″ N, 082°42′47″ W, thence to position 27°44′01″ N, 082°42′44″ W, thence to position 27°44′01″ N, 082°42′14″ W, thence to position 27°44′15″ N, 082°42′14″ W.

(b) *Definition.* The term ''designated representative'' means Coast Guard Patrol Commanders, including Coast Guard coxswains, petty officers, and other officers operating Coast Guard vessels, and Federal, state, and local officers designated by or assisting the Captain of the Port (COTP) St. Petersburg in the enforcement of the regulated areas.

(c) *Regulations.* (1) All non-participant persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within the ''race area'' unless an authorized by the COTP St. Petersburg or a designated representative.

(2) Vessel traffic within the ''buffer zone'' may be controlled by the COTP St. Petersburg or a designated representative as deemed necessary by the COTP St. Petersburg or a designated representative based upon prevailing weather conditions.

(3) Persons and vessels desiring to enter, transit through, anchor in, or remain within the race area contact the COTP St. Petersburg by telephone at (727) 824–7506 or via VHF–FM radio Channel 16 to request authorization.

(4) If authorization to enter, transit through, anchor in, or remain within the race area is granted, all persons and vessels receiving such authorization shall comply with the instructions of the COTP or a designated representative.

(5) The Coast Guard will provide notice of the regulated areas by Local Notice to Mariners, Broadcast Notice to Mariners, or by on-scene designated representatives.

(d) *Enforcement period.* This section will be enforced daily from 8 a.m. until 6 p.m. on March 27, 2020 through March 29, 2020.

Dated: March 10, 2020.

Matthew A. Thompson,

Captain, U.S. Coast Guard, Captain of the Port Saint Petersburg.

[FR Doc. 2020–05453 Filed 3–17–20; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2020–0165]

RIN 1625–AA00

Safety Zone, Atlantic Intracoastal Waterway, Camp Lejeune, NC

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the Atlantic Intracoastal Waterway at Camp Lejeune, North Carolina in support of military training exercises. This temporary safety zone is intended to restrict vessel traffic from a portion of the Atlantic Intracoastal Waterway between Mile Hammock Bay and

Onslow Beach Swing Bridge during military training operations. This action is intended to restrict vessel traffic on the Atlantic Intracoastal Waterway to protect mariners and training exercise participants from the hazards associated with military training operations. Entry of vessels or persons into this safety zone is prohibited unless specifically authorized by the Captain of the Port (COTP) North Carolina or designated representative.

DATES: This rule is effective from 6:00 a.m. on March 18, 2020, through 8:00 p.m. on March 19, 2020.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2020–0165 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, contact Petty Officer Matthew Tyson, Waterways Management Division, U.S. Coast Guard Sector North Carolina, Wilmington, NC; telephone: (910) 772–2221, email: *Matthew.I.Tyson@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 the Coast Guard was notified of the final details of the military training exercise on March 9, 2020. The Coast Guard must take immediate action to protect mariners and training exercise participants from the hazards associated with military training operations. It is impracticable and contrary to the public interest to publish an NPRM because a final rule needs to be in place by March 18, 2020, to minimize potential danger to mariners and training exercise participants.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable and contrary to public interest because immediate action is needed to protect mariners and training exercise participants from the hazards associated with military training operations beginning on March 18, 2020.

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 COTP North Carolina has determined that there are potential hazards associated with military training operations on the Atlantic Intracoastal Waterway at Camp Lejeune, North Carolina. This rule is necessary to protect safety of life from the potential hazards associated with military training operations.

IV. Discussion of the Rule

This rule establishes a safety zone from 6:00 a.m. on March 18, 2020, through 8:00 p.m. on March 19, 2020. The safety zone will include all navigable waters of the Atlantic Intracoastal Waterway from Mile Hammock Bay, approximate position 34°33′00″ N, 077°19′38″ W, to Onslow Beach Swing Bridge, approximate position 34°34′23″ N, 077°16′19″ W (NAD 1983). Part of the military training operations involves assembling a temporary bridge from shore to shore, completely blocking the navigable channel. To help facilitate commercial and recreational traffic, if vessels are waiting to transit, then the waterway will open every two hours to allow vessels to pass through the zone. On-scene safety personnel will direct vessels when it is safe to pass through the zone. The duration of this 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 unless specifically authorized by the Captain of the Port North Carolina or a designated representative.

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. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. 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), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size, location, and duration of the safety zone. The 38-hour regulation enforcement should not overly burden vessel traffic based on the short duration of the period and allows for vessels to pass through the zone every two hours if needed. This safety zone will only impact a small portion of the Atlantic Intracoastal Waterway at Camp Lejeune, NC and vessel traffic is expected to be low at this time of year. The Coast Guard will transmit a Broadcast Notice to Mariners via VHF–FM marine channel 16 regarding the safety zone. Vessels are prohibited from entering the safety zone unless specifically authorized by the Captain of the Port North Carolina or a designated representative.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this 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 involves a safety zone lasting 38 hours that will prohibit entry into a portion of the Atlantic Intracoastal Waterway at Camp Lejeune, NC. It is categorically excluded from further review under paragraph L(60)a of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

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

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T05–0165 to read as follows:

§ 165.T05–0165 Safety Zone; Atlantic Intracoastal Waterway, Camp Lejeune, NC.

(a) *Location.* The following area is a safety zone: All navigable waters of the Atlantic Intracoastal Waterway between Mile Hammock Bay, approximate position 34°33′00″ N, 77°19′38″ W, to Onslow Beach Swing Bridge approximate position 34°34′24″ N, 77°16′19″ W (NAD 1983) at Camp Lejeune, NC.

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

Captain of the Port means the Commander, Sector North Carolina.

Designated representative means a Coast Guard Patrol Commander, including a Coast Guard commissioned, warrant, or petty officer designated by the Captain of the Port North Carolina (COTP) for the enforcement of the safety zone.

Training exercise participants means persons and vessels involved in military training operations.

(c) *Regulations.* (1) The general regulations governing safety zones in § 165.23 apply to the area described in paragraph (a) of this section.

(2) With the exception of the training exercise particpants, entry into or remaining in this safety zone is prohibited unless authorized by the COTP North Carolina or the COTP North Carolina's designated representative. All other vessels must depart the zone immediately upon activation.

(3) Waiting vessels will be allowed to transit through the zone every two hours during enforcement, when directed by the Coast Guard, designated security vessels, or on-scene safety vessels.

(4) The Captain of the Port, North Carolina can be reached through the Coast Guard Sector North Carolina Command Duty Officer, Wilmington, North Carolina at telephone number 910–343–3882.

(5) The Coast Guard and designated security vessels enforcing the safety zone can be contacted on VHF–FM marine band radio channel 13 (165.65 MHz) and channel 16 (156.8 MHz).

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

(e) *Enforcement period.* This section will be enforced from 6:00 a.m. on March 18, 2020, through 8:00 p.m. on March 19, 2020.

Dated: March 12, 2020.

Bion B. Stewart,

Captain, U.S. Coast Guard, Captain of the Port North Carolina.

[FR Doc. 2020–05533 Filed 3–17–20; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2018–0832; FRL–10005–85]

Cyazofamid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of cyazofamid in or on multiple commodities that are identified and discussed later in this document. The Interregional Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective March 18, 2020. Objections and requests for hearings must be received on or before May 18, 2020, 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–2018–0832, is available at *https://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Michael Goodis, 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 EPA's tolerance regulations at 40 CFR part 180 through the Government Printing 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, 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–2018–0832 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 May 18, 2020. 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–2018–0832, by one of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *https://www.epa.gov/dockets/where-send-comments-epa-dockets.* Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of May 9, 2019 (84 FR 20320) (FRL–9992–36), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 8E8718) by IR–4, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201 W, Princeton, New Jersey 08540. The petition requested that 40 CFR 180.601 be amended by establishing tolerances for residues of the fungicide cyazofamid, 4-chloro-2-cyano-*N,N*-dimethyl-5-(4-methylphenyl)-1*H*-imidazole-1-sulfonamide, in or on brassica, leafy greens, subgroup 4–16B at 15.0 parts per million (ppm); ginseng at 0.2 ppm; kohlrabi at 1.5 ppm; leafy greens subgroup 4–16A at 10.0 ppm; and vegetable, brassica, head and stem, group 5–16 at 1.5 ppm. Upon the establishment of those tolerances, the petition requested the removal of existing tolerances for residues of the fungicide cyazofamid in or on brassica, head and stem, subgroup 5A at 1.2 ppm; brassica, leafy greens, subgroup 5B at 12.0 ppm; leafy greens subgroup 4A at 10 ppm; and turnip, greens at 12.0 ppm. That document referenced a summary of the petition prepared by ISK Biosciences Corporation, the registrant, which is available in the docket, *https://www.regulations.gov.* Two comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition and pursuant to its authority in FFDCA section 408(d)(4)(A)(i), EPA is establishing three of the tolerances at a different level than requested. The reasons for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the

pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for cyazofamid including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with cyazofamid follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its 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.

Cyazofamid belongs to a chemical class based on the cyanoimidazole and sulfonamide moieties. It specifically interferes with the cytochrome bc_1 complex (ubiquinol cytochrome *c* oxidoreductase) in the mitochondrial respiratory chain of oomycetes fungi. The mechanism of toxicity in mammals is not clear. There were no treatment-related adverse effects in the acute and subchronic neurotoxicity studies. However, following repeated administration in more than one species, toxicological effects were observed primarily in the kidney. There were no effects observed up to the limit dose (1,000 mg/kg) in the dermal toxicity study. In dogs, there were no major toxicity findings.

In the prenatal developmental toxicity study in rats, there was a marginal increased incidence of bent ribs observed in the high-dose (1,000 mg/kg/day) without any maternal effects, indicating quantitative susceptibility following *in utero* exposure.

Cyazofamid is classified as ''not likely to be carcinogenic to humans'' based on the lack of evidence of carcinogenicity in both the rat and the mouse studies. Additionally, cyazofamid does not appear to be mutagenic, based on several negative *in vivo* and *in vitro* studies.

Specific information on the studies received and the nature of the adverse effects caused by cyazofamid as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *https://www.regulations.gov* in document ''Cyazofamid. Human Health Risk Assessment for New Uses of Cyazofamid on Ginseng, and Greenhouse Cucumbers and Crop Group Conversions on Vegetable, Brassica, Head and Stem, Group 5–16; Brassica, Leafy Greens, Subgroup 4–16B; Leafy Greens, Subgroup 4–16A; and to Establish an Individual Tolerance on Kohlrabi'' on page 20 in docket ID number EPA–HQ–OPP–2018–0832.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks.*

A summary of the toxicological endpoints for cyazofamid used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of February 3, 2016 (81 FR 5602) (FRL–9940–46).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to cyazofamid, EPA considered exposure under the petitioned-for tolerances as well as all existing cyazofamid tolerances in 40 CFR 180.601. EPA assessed dietary exposures from cyazofamid in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies for cyazofamid; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used the food consumption data from the USDA 2003–2008 National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA included tolerance-level residues for all crops, default processing factors and assumed that 100% of the crops were treated (100% CT) with cyazofamid.

iii. *Cancer.* Based on the data cited in Unit III.A., EPA has concluded that cyazofamid does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for cyazofamid. Tolerance-level residues and/or 100% CT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment for cyazofamid in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of cyazofamid. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.*

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of cyazofamid for chronic exposures for non-cancer assessments are estimated to be 133.5

ppb for surface water and 211 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration value of 211 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Cyazofamid is currently registered for the following uses that could result in residential exposures: Turf and ornamentals. EPA assumes there is no residential handler exposure because labels require users to wear personal protective equipment. Post application exposure (to turf and ornamental) from hand-to-mouth exposures was greatest to children 1 to less than 2 years old. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide*.

4. *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.'' Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to cyazofamid and any other substances and cyazofamid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that cyazofamid has 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 *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides*.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* In the prenatal developmental toxicity study in rats, there was a marginal increased incidence of bent ribs observed at the high-dose (1,000 mg/kg/day) without any maternal effects, indicating quantitative susceptibility following *in utero* exposure. There is low concern for this effect because (1) bent ribs are a developmental variation rather than a malformation; (2) the increased incidence was only marginally increased over historical and concurrent controls; (3) similar effects were not seen in the rabbit developmental study; and (4) the effect was only observed at the limit dose.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for cyazofamid is complete.

ii. There is no indication that cyazofamid is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. Although there is evidence of quantitative susceptibility in the developmental rat study, the concern is low because the effects occur at the limit dose and are well-characterized with clearly established no observed adverse-effect level (NOAEL)/lowest-observed adverse-effect level (LOAEL) values and selected endpoints address the observed effects.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% CT, default processing factors and assumed tolerance-level residues for all crops. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to cyazofamid in drinking water. EPA used similarly conservative assumptions to assess post application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by cyazofamid.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, cyazofamid is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to cyazofamid from food and water will utilize 2.0% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of cyazofamid is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Cyazofamid is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to cyazofamid.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 6,200 for children 1 to less than 2 years old for dietary exposure (which is considered a background exposure) and incidental oral (hand-to-mouth) exposure from contact with

treated turf. Because EPA's level of concern for cyazofamid is an MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). An intermediate-term adverse effect was identified; however, cyazofamid is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for cyazofamid.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, cyazofamid is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to cyazofamid residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methods are available to determine residues of cyazofamid and its metabolite CCIM (4-chloro-5-(4-methylphenyl)-1*H*-imidazole-2-carbonitrile) in various commodities. An enforcement method for non-fatty commodities is available, FDA's Multiresidue Protocol D (without cleanup). The method completely recovers cyazofamid and its metabolite CCIM. In addition, the high-performance liquid chromatography method with ultraviolent light detection (HPLC/UV) method is acceptable for use as a single analyte enforcement method provided a confirmatory method such as the liquid chromatography method with tandem mass-spectrometric detection (LC/MS/MS) method is used.

The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has established MRLs for cyazofamid in or on Brassica (cole or cabbage) vegetables, head cabbage, and flowerhead Brassicas at 1.5 ppm; leaves of Brassicaceae at 15 ppm; and leafy vegetables (except Brassica leafy vegetables) at 10 ppm. The U.S. tolerances being established are harmonized with these Codex MRLs, specifically vegetable, brassica, head and stem, group 5–16 at 1.5 ppm; kohlrabi at 1.5 ppm; brassica leafy greens, subgroup 4–16B at 15 ppm; and leafy greens subgroup 4–16A at 10 ppm. There is no Codex MRL for ginseng.

C. Response to Comments

EPA received two comments to the Notice of Filing, generally opposed to any cyazofamid residues on leafy greens. Although the Agency recognizes that some individuals believe that pesticides should be banned on agricultural crops, the existing legal framework provided by section 408 of the FFDCA states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. These comments appear to be directed at the underlying statute and not EPA's implementation of it; the comments provide no information relevant the Agency's safety determination.

D. Revisions to Petitioned-For Tolerances

EPA is establishing tolerances for Brassica, leafy greens, subgroup 4–16B and Leafy greens subgroup 4–16A at different levels than requested to be consistent with the Organisation for Economic Cooperation and Development (OECD) rounding class practice. For ginseng, the petitioner's proposed tolerance was adjusted because storage stability data indicated a decline in residues of CCIM. Organization for Economic Cooperation and Development (OECD) statistical calculation procedures applied to the corrected residue data provided a different value (0.3 ppm) than the proposed value (0.2 ppm). Therefore, EPA is establishing the tolerance for ginseng at 0.3 ppm.

V. Conclusion

Therefore, tolerances are established for residues of cyazofamid, 4-chloro-2-cyano-*N,N*-dimethyl-5-(4-methylphenyl)-1*H*-imidazole-1-sulfonamide, in or on Brassica, leafy greens, subgroup 4–16B at 15 ppm; Ginseng at 0.3 ppm; Kohlrabi at 1.5 ppm; Leafy greens subgroup 4–16A at 10 ppm; and Vegetable, brassica, head and stem, group 5–16 at 1.5 ppm. Additionally, EPA is removing the established tolerances for Brassica, head and stem, subgroup 5A at 1.2 ppm; Brassica, leafy greens, subgroup 5B at 12.0 ppm; Leafy greens subgroup 4A at 10 ppm; and Turnip, greens at 12.0 ppm. Finally, as a housekeeping measure, EPA is removing the expired exemption in paragraph (b) Section 18 emergency exemptions for Basil, dried at 144 ppm, as it expired on December 31, 2014.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), nor is it considered a regulatory action under Executive Order 13771, entitled ''Reducing Regulations and Controlling Regulatory Costs,'' (82 FR 9339, February 3, 2017). This action does not contain any information

collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 2, 2020.

Michael Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.601:

■ a. In the table in paragraph (a):

■ i. Remove the entries: Brassica, head and stem, subgroup 5A; and Brassica, leafy greens, subgroup 5B;

■ ii. Add alphabetically the entries: Brassica, leafy greens, subgroup 4–16B; Ginseng; and Kohlrabi;

■ iii. Remove the entry Leafy greens subgroup 4A;

■ iv. Add alphabetically the entry Leafy greens subgroup 4–16A;

■ v. Remove the entry Turnip, greens; and

■ vi. Add alphabetically the entry Vegetable, brassica, head and stem, group 5–16; and

■ b. Remove and reserve paragraph (b).

The additions and revision read as follows:

§ 180.601 Cyazofamid; tolerances for residues.

(a) * * *

TABLE TO PARAGRAPH (A)

Commodity	Parts per million
* * * * *	
Brassica, leafy greens, subgroup 4–16B	15
* * * * *	
Ginseng	0.3
* * * * *	
Kohlrabi	1.5
Leafy greens subgroup 4–16A	10
Vegetable, brassica, head and stem, group 5–16	1.5
* * * * *	

* * * * *

[FR Doc. 2020–04747 Filed 3–17–20; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 600

[Docket No. 200313–0080]

RIN 0648–BI82

Clarification of Magnuson-Stevens Fishery Conservation and Management Act Regulation Regarding Monitor National Marine Sanctuary; Final Rulemaking

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

ACTION: Final rule.

SUMMARY: This final rule will clarify a regulation adopted under the Magnuson-Stevens Fishery Conservation and Management Act (MSA), which cross-references and incorrectly interprets regulations adopted under the National Marine Sanctuaries Act. The Monitor National Marine Sanctuary (Sanctuary) regulations currently prohibit some, but not all, fishing in the Sanctuary. NMFS is clarifying its regulation which incorrectly interprets Sanctuary regulations to prohibit all fishing in the Sanctuary by removing the fishing prohibition text and cross-referencing regulations for national marine sanctuaries.

DATES: The final rule is effective March 18, 2020.

FOR FURTHER INFORMATION CONTACT: Chris Wright, Fishery Policy Analyst, 301–427–8504, or via email *chris.wright@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Sanctuary was designated as the nation's first national marine sanctuary in 1975 and protects the wreck of the famed Civil War ironclad U.S.S. Monitor. This proposed rule would amend a general fishery regulation adopted under the MSA, which currently provides: ''[a]ll fishing activity, regardless of species sought, is prohibited under 15 CFR part 924 in the U.S.S. Monitor Marine Sanctuary, which is located approximately 15 miles southwest of Cape Hatteras off the coast of North Carolina'' (50 CFR 600.705(f)). This text incorrectly states that ''all fishing activity'' is prohibited under national marine sanctuary regulations. The Sanctuary regulations, which are currently codified at part 922, only expressly prohibit one type of fishing

activity, ''trawling'' (50 CFR 922.61(h)). The Sanctuary regulations further prohibit all ''dredging'' and ''[a]nchoring in any manner, stopping, remaining, or drifting without power'' (Id. § 922.61(a)). While these regulations limit some fishing activity, it is incorrect to state that all fishing is prohibited in the Sanctuary by national marine sanctuary regulations, as the current NMFS regulation provides.

On December 16, 2019, NMFS issued a proposed rule (84 FR 68389) to clarify the regulatory text at 50 CFR 600.705(f) by removing the incorrect text and retaining a cross-reference to the Office of National Marine Sanctuaries' regulations at 15 CFR part 922, which regulate activities in the national marine sanctuaries. The regulation we are amending is in the General Provisions for Domestic Fisheries (50 CFR part 600, subpart H). Regulations in part 600 implement and carry out all domestic fishery management plans (FMPs) adopted under the MSA. This action is authorized under MSA § 305(d), which gives the Agency general authority to carry out FMPs adopted under the MSA.

Comments and Responses

NMFS received four comments during the comment period. All written comments can be found at *http://www.regulations.gov/* by searching for RIN 0648–BI82. The comments received during the comment period are summarized below.

Comment 1: The South Atlantic Fishery Management Council supports the proposed rule because it alleviates confusion regarding fishing regulations in the Sanctuary by removing the text that prohibits ''all fishing activity.'' The Council stated the remaining specific regulations that prohibit anchoring, trawling, drifting, diving, and lowering devices below the surface strike a reasonable balance between protecting the historic site and allowing limited fishing activity that will not impact the site.

NMFS agrees with this comment because it reiterates the Agency's rationale for this action.

Comment 2: The North Carolina Division of Marine Fisheries supports the proposed rule because it removes the prohibition on all fishing activity in the regulatory text and references the appropriate regulations. They agree with NMFS that this action will remove unnecessary regulations, the net economic impact will be positive, and the modifications will potentially alleviate confusion among stake holders.

NMFS agrees with this comment because it reiterates the Agency's rationale for this action.

Comment 3: Two commenters, from the general public, did not support the proposed rule and asked NMFS to prohibit all fishing in the Sanctuary.

NMFS disagrees with these comments. Nothing in the National Marine Sanctuaries Act requires NOAA to prohibit all fishing in national marine sanctuaries. NOAA's Office of National Marine Sanctuaries believes that national marine sanctuaries should take into account various stakeholders and activities as long as they do not conflict with the primary goal of resource protection. The current Sanctuary regulations strike a balance of protecting the U.S.S. Monitor while allowing for some fishing to occur.

Classification

This final rule is promulgated pursuant to MSA § 305(d). The NMFS Assistant Administrator has determined that this rule is consistent with the MSA and other applicable law.

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

This final rule is considered an Executive Order 13771 deregulatory action. NMFS expects this final rule to alleviate the potential for confusion regarding the fishing allowed in the Sanctuary, by making clear that NMFS does not interpret Sanctuary regulations to prohibit all fishing in the Sanctuary. This final rule also makes clear that regulations governing fishing in national marine sanctuaries are set forth at 15 CFR part 222 and that these regulations may apply in addition to regulations adopted under the MSA.

No duplicative, overlapping, or conflicting Federal rules have been identified beyond those discussed herein. In addition, no new reporting, recordkeeping, or other compliance requirements are introduced by this final rule. Accordingly, the Paperwork Reduction Act does not apply to this final rule.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration during the proposed rule stage that this rule would not have a significant economic impact on a substantial number of small entities. The factual basis for this determination was published in the proposed rule and is not repeated here. None of the public comments that were received specifically addressed the certification and NMFS has not received any new information that would affect its determination that this rule would not have a significant economic impact on a substantial number of small entities. As a result, a final regulatory flexibility analysis was not required and none was prepared.

There is good cause under 5 U.S.C. 553(d)(3) to waive the 30-day delay in effective date. NMFS' regulation at 50 CFR 600.705(f) currently interprets national marine sanctuary regulations incorrectly. This has the potential to create confusion regarding the fishing restrictions applicable to the Sanctuary and should be corrected as expeditiously as possible. The impact if this action is not implemented immediately is the continued potential for confusion from the public and the recreational and commercial fishing sectors in regard to the Sanctuary's fishing regulations.

List of Subjects in 50 CFR Part 600

Fisheries, Fishing, Reporting and recordkeeping requirements.

Dated: March 13, 2020.

Samuel D. Rauch III,

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

For the reasons stated in the preamble, 50 CFR part 600 will be amended as follows:

PART 600—MAGNUSON-STEVENS ACT PROVISIONS

■ 1. The authority citation for part 600 continues to read as follows:

Authority: 5 U.S.C. 561 and 16 U.S.C. 1801 *et seq.*

■ 2. In § 600.705, revise paragraph (f) to read as follows:

§ 600.705 Relation to other laws.

* * * * *

(f) *Marine sanctuaries.* Regulations governing fishing activities inside the boundaries of national marine sanctuaries are set forth in 15 CFR part 922.

* * * * *

[FR Doc. 2020–05649 Filed 3–17–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 2020–04016]

RTID 0648–XY072

Fisheries of the Exclusive Economic Zone Off Alaska; Pollock in the West Yakutat District of the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and

Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for pollock in the West Yakutat District of the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the 2020 total allowable catch of pollock in the West Yakutat District of the GOA.

DATES: Effective 1200 hours, Alaska local time (A.l.t.), March 13, 2020, through 2400 hours, A.l.t., December 31, 2020.

FOR FURTHER INFORMATION CONTACT: Josh Keaton, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2020 total allowable catch (TAC) of pollock in the West Yakutat District of the GOA is 5,554 metric tons (mt) as established by the final 2020 and 2021 harvest specifications for groundfish in the GOA (85 FR 13802, March 10, 2020).

In accordance with § 679.20(d)(1)(i), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that the 2020 TAC of pollock in the West Yakutat District of the GOA will soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 5,354 mt, and is setting aside the remaining 200 mt as bycatch to support other anticipated groundfish fisheries. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for pollock in the West Yakutat District of the GOA.

After the effective date of this closure the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the closure of directed fishing for pollock in the West Yakutat District of the GOA. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of March 12, 2020.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

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

Dated: March 13, 2020.

Karyl K. Brewster-Geisz,

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

[FR Doc. 2020–05597 Filed 3–13–20; 4:15 pm]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 200221–0062]

RTID 0648–XY083

Fisheries of the Exclusive Economic Zone Off Alaska; Pollock in Statistical Area 610 in the Gulf of Alaska

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for pollock in Statistical Area 610 in the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the B season allowance of the 2020 total allowable catch of pollock for Statistical Area 610 in the GOA.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), March 14, 2020, through 1200 hrs, A.l.t., May 31, 2020.

FOR FURTHER INFORMATION CONTACT: Josh Keaton, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The B season allowance of the 2020 total allowable catch (TAC) of pollock in Statistical Area 610 of the GOA is 517 metric tons (mt) as established by the final 2020 and 2021 harvest specifications for groundfish in the GOA (85 FR 13802, March 10, 2020).

In accordance with § 679.20(d)(1)(i), the Regional Administrator has determined that the B season allowance of the 2020 TAC of pollock in Statistical Area 610 of the GOA is necessary to account for the incidental catch in other anticipated fisheries. Therefore, the Regional Administrator is establishing a directed fishing allowance of 0 mt and is setting aside the remaining 517 mt as bycatch to support other anticipated groundfish fisheries. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for pollock in Statistical Area 610 of the GOA.

While this closure is effective the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the closure of directed fishing for pollock in Statistical Area 610 of the GOA. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of March 12, 2020.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of

prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

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

Dated: March 13, 2020.

Karyl K. Brewster-Geisz,

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

[FR Doc. 2020–05598 Filed 3–13–20; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 85, No. 53
Wednesday, March 18, 2020

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.

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 34, 36, and 39

[NRC–2019–0031]

RIN 3150–AK29

Individual Monitoring Devices

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations to authorize the use of modern individual monitoring devices in industrial radiographic, irradiator, and well logging operations. The proposed amendments would align personnel dosimetry requirements in these areas with the requirements for all other NRC licensees. This proposed rule addresses an issue raised in a petition for rulemaking and would affect NRC and Agreement State licensees. The NRC also is issuing supplemental guidance for use and comment.

DATES: Submit comments by April 17, 2020. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date.

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

- *Federal Rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2019–0031. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Email comments to: Rulemaking.Comments@nrc.gov.* If you do not receive an automatic email reply confirming receipt, then contact us at 301–415–1677.
- *Fax comments to:* Secretary, U.S. Nuclear Regulatory Commission at 301–415–1101.
- *Mail comments to:* Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Rulemakings and Adjudications Staff.
- *Hand deliver comments to:* 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. (Eastern Time) Federal workdays; telephone: 301–415–1677.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Anthony McMurtray, telephone: 301–415–2746; email: *Anthony.McMurtray@nrc.gov;* or Edward Lohr, telephone: 301–415–0253; email: *Edward.Lohr@nrc.gov.* Both are staff of the Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Obtaining Information and Submitting Comments
II. Rulemaking Procedure
III. Background
IV. Plain Writing
V. Paperwork Reduction Act

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2019–0031 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2019–0031.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2019–0031 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Rulemaking Procedure

Because the NRC considers this action to be non-controversial, the NRC is publishing this proposed rule concurrently with a direct final rule in the Rules and Regulations section of this issue of the **Federal Register**. The direct final rule will become effective on June 16, 2020. However, if the NRC receives significant adverse comments by April 17, 2020, then the NRC will publish a document that withdraws the direct final rule and the associated supplemental guidance. If the direct final rule is withdrawn, the NRC will address the comments if there is a subsequent final rule. Absent significant modifications to the proposed revisions requiring republication, the NRC will not initiate a second comment period on this action in the event the direct final rule is withdrawn.

A significant adverse comment is a comment where the commenter explains why the rule would be inappropriate, including challenges to the rule's underlying premise or

approach, or would be ineffective or unacceptable without a change. A comment is adverse and significant if:

(1) The comment opposes the rule and provides a reason sufficient to require a substantive response in a notice-and-comment process. For example, a substantive response is required when:

(a) The comment causes the NRC to reevaluate (or reconsider) its position or conduct additional analysis;

(b) The comment raises an issue serious enough to warrant a substantive response to clarify or complete the record; or

(c) The comment raises a relevant issue that was not previously addressed or considered by the NRC.

(2) The comment proposes a change or an addition to the rule, and it is apparent that the rule would be ineffective or unacceptable without incorporation of the change or addition.

(3) The comment causes the NRC to make a change (other than editorial) to the rule.

For procedural information and the regulatory analysis, see the direct final rule published in the Rules and Regulations section of this issue of the **Federal Register**.

III. Background

The regulations in part 34 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations''; 10 CFR part 36, ''Licenses and Radiation Safety Requirements for Irradiators''; and 10 CFR part 39, ''Licenses and Radiation Safety Requirements for Well Logging,'' require the use of personnel dosimetry that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor. These regulations restrict the types of personnel dosimeters that can be used and prohibit the use of newer dosimetry technologies that do not require processing by an accredited NVLAP facility.

On July 14, 2016, the NRC received a petition for rulemaking (PRM) from the American Society for Nondestructive Testing and the Nondestructive Testing Management Association (the petitioners) (ADAMS Accession No. ML16228A045). The petition was docketed by the NRC on August 12, 2016, and assigned Docket No. PRM–34–7. The NRC published a notice of docketing of PRM–34–7 in the **Federal Register** (81 FR 78732) on November 9, 2016. The petitioners requested that the NRC amend its regulations and associated guidance to authorize the use of improved individual monitoring devices for industrial radiographic personnel. Specifically, the petitioners requested that the NRC amend its regulations to authorize the use of digital output personnel dosimeters to satisfy the personnel dosimetry requirements in § 34.47(a). The petitioners interchangeably used the terms ''improved individual monitoring devices,'' ''electronic personnel monitoring dosimeters,'' ''electronic dosimeters,'' and ''digital personnel dosimeters'' to describe digital output personnel dosimetry. In this proposed rule, the NRC uses the term ''digital output personnel dosimetry'' in place of these terms. A digital output personnel dosimeter is a specific type of personnel dosimetry that currently cannot be used to meet the requirements in 10 CFR parts 34, 36, and 39 to demonstrate compliance with the occupational dose limits in § 20.1201. The NRC published a notice of docketing of PRM–34–7 in the **Federal Register** (81 FR 78732) on November 9, 2016.

On February 11, 2019, the NRC published a document in the **Federal Register** (84 FR 3116) informing the public that it would consider PRM–34–7 in the rulemaking process. In the **Federal Register** notice, the NRC accepted the petitioners' request that the NRC amend its regulations to authorize the use of digital output personnel dosimeters for industrial radiographic personnel and expanded the scope of the rulemaking to include the use of digital output personnel dosimeters in irradiator and well logging operations.

IV. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111–274) requires Federal agencies to write documents in a clear, concise, well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, ''Plain Language in Government Writing,'' published June 10, 1998 (63 FR 31885). The NRC requests comment on the proposed rule with respect to clarity and effectiveness of the language used.

V. Paperwork Reduction Act

This proposed rule does not contain any new or amended collections of information subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Existing collections of information were approved by the Office of Management and Budget, approval numbers 3150–0007, 3150–0130, and 3150–0158.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

List of Subjects

10 CFR Part 34

Criminal penalties, Manpower training programs, Occupational safety and health, Packaging and containers, Penalties, Radiation protection, Radiography, Reporting and recordkeeping requirements, Scientific equipment, Security measures, X-rays.

10 CFR Part 36

Byproduct material, Criminal penalties, Nuclear energy, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment, Security measures.

10 CFR Part 39

Byproduct material, Criminal penalties, Labeling, Nuclear energy, Nuclear material, Occupational safety and health, Oil and gas exploration—well logging, Penalties, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment, Security measures, Source material, Special nuclear material.

Dated at Rockville, Maryland, this 3rd day of March, 2020.

For the Nuclear Regulatory Commission.

Margaret M. Doane,

Executive Director for Operations.

[FR Doc. 2020–05296 Filed 3–17–20; 8:45 am]

BILLING CODE 7590–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 30

[EPA–HQ–OA–2018–0259; FRL–10004–72–ORD]

RIN 2080–AA14

Strengthening Transparency in Regulatory Science

AGENCY: Environmental Protection Agency (EPA).

ACTION: Supplemental notice of proposed rulemaking.

SUMMARY: This supplemental notice of proposed rulemaking (SNPRM) includes clarifications, modifications and additions to certain provisions in the Strengthening Transparency in Regulatory Science Proposed

Rulemaking (''2018 proposed rulemaking,'' Ref. 1), published on April 30, 2018. This SNPRM proposes that the scope of the rulemaking apply to influential scientific information as well as significant regulatory decisions. This notice proposes definitions and clarifies that the proposed rulemaking applies to data and models underlying both pivotal science and pivotal regulatory science. In this SNPRM, EPA is also proposing a modified approach to the public availability provisions for data and models that would underly significant regulatory decisions and an alternate approach. Finally, EPA is taking comment on whether to use its housekeeping authority independently or in conjunction with appropriate environmental statutory provisions as authority for taking this action.

DATES: Comments must be received on or before April 17, 2020.

ADDRESSES: You may send comments, identified by Docket ID No. EPA–HQ–OA–2018–0259, by any of the following methods:

Federal eRulemaking Portal: https://www.regulations.gov/ (our preferred method). Follow the online instructions for submitting comments.

Mail: U.S. Environmental Protection Agency, EPA Docket Center, Office of Research and Development Docket, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.

Hand Delivery/Courier: EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Docket Center's hours of operations are 8:30 a.m.—4:30 p.m., Monday—Friday (except Federal Holidays).

Instructions: All submissions received must include the Docket ID No. for this rulemaking. Comments received may be posted without change to *https://www.regulations.gov/,* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Cheryl A. Hawkins, Office of Science Advisor, Policy and Engagement (8104R), Environmental Protection Agency, 1200 Pennsylvania Ave NW, Washington, DC 20460; telephone number: (202) 564–7307; email address: *osp_staff@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

This SNPRM does not regulate any entity outside the Federal Government. Rather, the proposed requirements would modify the EPA's internal procedures regarding the transparency of science underlying regulatory decisions. However, the Agency recognizes that any entity interested in EPA's regulations may be interested in this proposal. For example, this proposal may be of particular interest to entities that conduct research or another scientific activity that is likely to be relevant to EPA's regulatory activity.

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

On April 30, 2018, in the **Federal Register** at 83 FR 18768 EPA published the Strengthening Transparency in Regulatory Science Proposed Rulemaking (''2018 proposed rulemaking,'' Ref. 1). The 2018 proposed rulemaking cites as authority several environmental statutes that EPA administers: The Clean Air Act; the Clean Water Act; the Safe Drinking Water Act; the Resource Conservation and Recovery Act; the Comprehensive Environmental Response, Compensation, and Liability Act; the Federal Insecticide, Fungicide, and Rodenticide Act; the Emergency Planning and Community Right-To-Know Act and the Toxic Substances Control Act. Subsequently, in the **Federal Register** at 83 FR 24255, May 25, 2018, EPA published a document extending the comment period and announcing a public hearing on the 2018 proposed rulemaking to be held on July 18, 2018 (Ref. 2). That document identified 5 U.S.C. 301 as a source of authority in addition to those statutes cited in the 2018 proposed rulemaking. With respect to the authorities cited in the 2018 proposal, EPA is clarifying that the citation to the Resource Conservation and Recovery Act (''RCRA'') section 7009, 42 U.S.C. 6979, should be to RCRA section 8001, 42 U.S.C. 6981; the citation to the Comprehensive Environmental Response, Compensation, and Liability Act (''CERCLA'') section 116, 42 U.S.C. 9616, should be to CERCLA section 115, 42 U.S.C. 9615; and including the Clean Water Act section 501, 33 U.S.C. 1361.

EPA is authorized to promulgate this regulation under its housekeeping authority. The Federal Housekeeping Statute provides that ''[t]he head of an Executive department or military department may prescribe regulations for the government of his department, the conduct of its employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property.'' 5 U.S.C. 301. As the Supreme Court discussed in *Chrysler Corp* v. *Brown,* the intended purpose of section 301 was to grant early Executive departments the authority ''to govern internal departmental affairs.'' [1] As the Supreme Court further notes, section 301 authorizes ''what the [Administrative Procedure Act] terms 'rules of agency organization, procedure or practice' as opposed to substantive rules.'' [2]

EPA is not one of the 15 ''Executive Departments'' listed at 5 U.S.C. 101. However, EPA gained housekeeping authority through the Reorganization Plan No. 3 of 1970, 84 Stat. 2086 (July 9, 1970). The Reorganization Plan created EPA, established the Administrator as ''head of the agency'' and transferred functions and authorities of various agencies and Executive departments to EPA.

Section 2(a)(1)–(8) of the Reorganization Plan transferred to EPA functions previously vested in several agencies and executive departments including the Departments of Interior and Agriculture. Section 2(a)(9) also transferred so much of the functions of the transferor officers and agencies ''as is incidental to or necessary for the performance by or under the Administrator of the functions transferred.''

The Office of Legal Counsel has opined that the Reorganization Plan ''convey[s] to the [EPA] Administrator all of the housekeeping authority available to other department heads under section 301'' and demonstrates that ''Congress has vested the Administrator with the authority to run EPA, to exercise its functions, and to issue regulations incidental to the performance of those functions.'' [3]

Courts have considered EPA to be an agency with section 301 housekeeping authority. The U.S. Court of Appeals for the Second Circuit, in *EPA* v. *General Elec. Co.,* 197 F.3d 592, 595 (2d Cir. 1999), found that ''the Federal Housekeeping Statute, 5 U.S.C. 301, authorizes government agencies such as the EPA to adopt regulations regarding 'the custody, use, and preservation of [agency] records, papers, and property.' '' The Fourth Circuit Court of Appeals, in *Boron Oil Co.* v. *Downie,* 873 F.2d 67, 69 (4th Cir. 1989), held that the district court exceeded its jurisdiction where it compelled testimony contrary to duly promulgated EPA regulations which EPA argued were authorized by section 301.

EPA's housekeeping authority was established by the Reorganization Plan.

[1] *Chrysler Corp.* v. *Brown,* 441 U.S. 281, 309 (1979).

[2] *Id.* at 310.

[3] Authority of EPA to Hold Employees Liable for Negligent Loss, Damage, or Destruction of Government Personal Property, 32 O.L.C. 79, 2008 WL 4422366 at *4 (May 28, 2008) (''OLC Opinion'').

As indicated by the case law and the OLC Opinion, it has long been recognized that EPA has been granted full section 301 or equivalent authority. Therefore, EPA has ample authority to promulgate regulations that govern internal agency procedures.

The 2018 proposed rulemaking, as supplemented by this SNPRM and this accompanying preamble, describes how EPA will handle studies when data and models underlying science that is pivotal to EPA's significant regulatory decisions or influential scientific information are or are not publicly available in a manner sufficient for independent validation and analysis. The rule would not regulate the conduct or determine the rights of any entity outside the federal government.[4] Rather, it exclusively pertains to the internal practices of the EPA.

Finally, EPA in the 2018 proposed rulemaking, as supplemented by this SNPRM and this accompanying preamble, does not propose to interpret provisions of a particular statute or statutes that it administers. Instead, in this action, EPA proposes a rule of agency procedure to establish an agency wide approach to handling studies when the data and models underlying EPA's significant regulatory decisions and influential scientific information are publicly available and when those data and models are not publicly available. Therefore, this is a proposed internal rule of agency procedure.

This internal agency procedure is intended to be consistent with the statutes that EPA administers and EPA plans to implement this procedural rulemaking in accordance with all applicable statutory and regulatory requirements. Indeed, as discussed in this SNPRM, EPA is also proposing options that would allow EPA to consider studies even if the underlying data and models are not publicly available. [See Section IV.] The Agency seeks comment on whether this approach may improve consistency between this proposed rulemaking and certain provisions of those statutes that refer to standards for data availability. Nonetheless, in the event the procedures outlined in the proposed rulemaking conflict with the statutes that EPA administers, or their implementing regulations, the statutes and regulations will control. Moreover, EPA is considering how to proceed, apart from this supplemental proposal, to establish regulations interpreting provisions of, and/or exercising substantive rulemaking authority delegated to it by programmatic statutes, to include one or more of those statutes cited as authority in the 2018 proposed rulemaking as clarified in this SNPRM.

Although this is a rule of internal agency procedure and EPA does not propose to interpret provisions of a particular statute or statutes that it administers, EPA is taking comment on whether to use its housekeeping authority independently as authority or in conjunction with the environmental statutory provisions cited as authority in the 2018 proposed rulemaking (as clarified in this SNPRM). The Agency continues to consider whether it is appropriate to rely on its authority in the above-reference environmental statutory provisions (potentially in conjunction with its housekeeping authority). The Agency will consider comments on this issue submitted in response to the 2018 proposal and in response to this SNPRM.

C. What action is the Agency taking?

EPA is issuing this SNPRM to clarify, modify and supplement certain provisions included in the 2018 proposed rulemaking in response to some of the public comments received on the 2018 proposed rulemaking (83 FR 18768), as well as to ensure consistency with the April 2019 release of the White House's Office of Management and Budget (OMB) Memorandum to the Heads of Executive Departments and Agencies entitled Implementation of the Information Quality Act (OMB M–19–15, Ref. 3). This memorandum is directly relevant to several of the provisions of the 2018 proposed rulemaking because it updates implementation of OMB's 2002 Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies to, among other things, reflect recent innovations and policies surrounding information access.

First, EPA is modifying the regulatory text initially proposed in the 2018 proposed rulemaking at 40 CFR 30.3, 30.5, 30.6 and 30.9 so that these provisions would apply to data and models, not only dose-response data and dose-response models. In addition, EPA is clarifying that the use of the terms ''model assumptions'' and ''models'' in the proposed regulatory text at 40 CFR 30.6 apply to the assumptions that drive the model's analytic results. EPA has modified the regulatory text at 40 CFR 30.6 to reflect this clarification. This approach is consistent with OMB M–19–15 (Ref. 3), which highlights the need to characterize the sensitivity of an agency's conclusions to analytic assumptions.

Second, EPA is proposing to expand the scope of this rulemaking to apply to influential scientific information[5] [6] as well as significant regulatory actions. EPA is proposing to add definitions for ''influential scientific information'' and ''pivotal science'' at 40 CFR 30.2 that will pertain to the science underlying influential scientific information, which are not regulatory, and is making conforming changes to proposed 40 CFR 30.3, 30.5, 30.6 and 30.7. EPA is retaining the definition of ''pivotal regulatory science'' from the 2018 proposed rulemaking regulatory text.

Third, EPA is modifying, deleting and proposing new regulatory text in addition to proposing definitions for ''influential scientific information'' and ''pivotal science'' at proposed 40 CFR 30.2. EPA is deleting the first paragraph of the 2018 proposed rulemaking regulatory text at 40 CFR 30.2. EPA is deleting the definition of ''research data'' at 40 CFR 30.2. EPA is proposing definitions for the terms ''Capable of being substantially reproduced'', ''Data'', ''Independent validation'', ''Influential scientific information,'' ''Model'', ''Pivotal science'', ''Publicly available'' and ''Reanalyze.'' These revisions are intended to provide clarity on key terminology used in the regulatory text in the 2018 proposed rulemaking as well as in this supplemental proposal.

Fourth, EPA is deleting the 2018 proposed regulatory text at 40 CFR 30.10. This change is being made to be consistent with the deletion of ''research data'' in 40 CFR 30.2 because 40 CFR 30.10 would have required EPA to implement this rulemaking to be consistent with the definition of ''research data.'' With the deletion of

[4] *See also United States* v. *Manafort,* 312 F. Supp. 3d 60, 75 (D.D.C. 2018) (explaining that the Department of Justice ''was not at all ambiguous about what it was doing when it promulgated the Special Counsel Regulations [under the authority of 5 U.S.C. 301], and it emphasized that it was not creating a substantive rule.'').

[5] The term ''influential scientific information'' means scientific information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions (OMB M–05–03). A ''highly influential scientific assessment'' is a subset of influential scientific information and refers to ''an evaluation of a body of scientific or technical knowledge that typically synthesizes multiple factual inputs, data, models, assumptions, and/or applies best professional judgment to bridge uncertainties in the available information'' and that the dissemination of such assessment could have ''a potential impact of more than $500 million in any one year on either the public or private sector or that the dissemination is novel, controversial, or precedent-setting, or has significant interagency interest'' (OMB M–05–03).

[6] See EPA's Peer Review Agenda at *https://cfpub.epa.gov/si/si_public_pr_agenda.cfm.*

''research data'' from proposed 40 CFR 30.2, proposed 40 CFR 30.10 is no longer needed.

Fifth, EPA is proposing a modified version of the regulatory text at 40 CFR 30.5 from that proposed in the 2018 proposed rulemaking. Under this new approach to proposed 40 CFR 30.5, when promulgating significant regulatory decisions or finalizing influential scientific information, the Agency will only use pivotal regulatory science and/or pivotal science if the data and models are available in a manner sufficient for independent validation. This includes studies with data and models that are publicly available as well as studies with restricted data and models (*i.e.,* those that include confidential business information (CBI), proprietary data, or Personally Identifiable Information (PII) that cannot be sufficiently de-identified to protect the data subjects) if there is tiered access to these data and models in a manner sufficient for independent validation. Tiered access includes the appropriate techniques used to reduce the risk of re-identification and, therefore, mitigate certain disclosure privacy risks associated with providing such access.

As an alternative, EPA is proposing that under proposed 40 CFR 30.5, when promulgating significant regulatory decisions or finalizing influential scientific information, other things being equal, the Agency will give greater consideration to studies where the underlying data and models are available in a manner sufficient for independent validation either because they are publicly available or because they are available through tiered access when the data includes CBI, proprietary data, or PII that cannot be sufficiently de-identified to protect the data subjects. The Agency will identify those studies that are given greater consideration and will provide a short description of why greater consideration was given. As discussed later in the preamble, such approaches to increasing access to data and models can often allow stakeholders to reanalyze the data and models and explore the sensitivity of the conclusions to alternative assumptions while accessing only the data and aspects of the models that they need. This proposal would apply to reviews of data, models, and studies at the time a rule is developed or influential scientific information is finalized, regardless of when the data and models were generated. See Section IV of this preamble for a description of these proposals.

Sixth, EPA is modifying 40 CFR 30.9 to describe the factors the Administrator would consider in determining whether to grant an exemption to the proposed public availability requirements for using data and models in significant regulatory decisions and influential scientific information.

Seventh, the EPA is proposing the option of using its housekeeping authority independently as authority for taking this action or in conjunction with the environmental statutory provisions cited as authority in the 2018 proposed rulemaking (as clarified in this supplemental proposal). The Agency continues to consider whether it is appropriate to rely on its authority in the above-referenced environmental statutory provisions (potentially in conjunction with its housekeeping authority). The Agency will consider comments on this issue submitted in response to the 2018 proposal and in response to this SNPRM. Section 301 authority as transferred to EPA in Reorganization Plan No. 3 of 1970 provides appropriate authority for EPA to promulgate regulations that govern internal agency procedures. This action establishes internal agency procedures governing how EPA employees will handle studies when the data and models underlying science that is pivotal to EPA's significant regulatory decisions and/or influential scientific information are or are not publicly available.

The 2018 proposed rulemaking solicited comment on all aspects of the proposed rulemaking. This SNPRM solicits comment only on the changes and additions to the proposed regulatory text discussed in this supplemental document. Comments submitted in response to this supplemental document that address aspects of the 2018 proposed rulemaking that are not addressed, altered, or replaced by this SNPRM will be deemed outside the scope of this supplemental action.

D. Why is the Agency taking this action?

EPA received extensive comment on the 2018 proposed rulemaking regarding the clarity of certain aspects of the proposed rulemaking and the challenges in making all dose-response data and models publicly available. The intent of this supplemental proposal SNPRM is to address certain concerns raised about the clarity of the 2018 proposed rulemaking; to clarify consistency with OMB M–19–15, OMB M–05–03 (Final Information Quality Bulletin for Peer-Review, Ref. 4), and Executive Order 13891 (Ref. 5); to propose an alternate 40 CFR 30.5 provision for availability of data and models underlying pivotal regulatory science and pivotal science, and to propose relying on 5 U.S.C. 301 independently or in conjunction with the environmental statutory provisions cited as authority in the 2018 proposed rulemaking (as clarified in this SNPRM). The Agency continues to consider whether it is appropriate to rely on its authority in the above-reference environmental statutory provisions (potentially in conjunction with its housekeeping authority). The Agency will consider comments on this issue submitted in response to the 2018 proposal rulemaking and in response to this SNPRM.

II. Applicability to Data and Models

As identified by some public commenters, the 2018 proposed rulemaking did not put its discussion of increasing access to the data and models underlying pivotal regulatory science into the context of the broader approach that EPA uses to evaluate the entire body of scientific literature—that is, before it identifies candidates for ''pivotal regulatory science.'' Under this regulation EPA would continue to use standard processes for identifying, evaluating, and reviewing available data, models, and studies. When the Agency has potentially identified multiple key studies or models of similar quality that could drive its subsequent decisions, the Agency will investigate the availability of the underlying data. If, for example, multiple high-quality studies exist but only two studies have data and models that are available for independent validation and reanalysis, EPA would only include those two studies as pivotal regulatory science and/or pivotal science in accordance with the 2018 proposed rulemaking. However, under the alternative approach in this supplemental proposal, EPA would consider using all available high-quality studies but give greater consideration to those two studies with data available for independent validation.

As highlighted in some public comments, the terms ''dose-response data and models,'' ''dose-response models,'' ''models'' and ''model assumptions'' are not used consistently throughout the regulatory text of the 2018 proposed rulemaking. For example, some parts of the regulatory text appear to limit applicability of certain provisions to only dose-response models.[7] In others, the requirements would apply more broadly. EPA is now proposing a broader applicability. Transparency of EPA's science should not be limited to dose-response data and dose-response models, because other

[7] See § 30.6.

types of data and models will also drive the requirements and/or quantitative analysis of EPA final significant regulatory decisions and influential scientific information.

EPA is modifying the proposed regulatory text at 40 CFR 30.3, 30.5, 30.6 and 30.9 by deleting the term ''dose-response,'' except in one instance. In proposed 40 CFR 30.6, EPA is not deleting ''dose response'' from the sentence specific to parametric dose-response models. EPA is also removing ''including assumptions of a linear, no-threshold dose response'' from 40 CFR 30.6, because this could imply that the regulation is specific to those particular assumptions. This is not the intent of proposed 40 CFR 30.6.

Consistent with this broader approach to transparency, the proposed requirements of this rule would apply broadly to data and models underlying pivotal regulatory science and pivotal science which support significant regulatory decisions and influential scientific information, respectively, rather than simply to dose-response data and models. Some, but not the only, examples of information that would be considered to be data and models, in addition to dose-response data and dose-response models, include environmental fate studies, bioaccumulation data, water-solubility studies, environmental fate models, engineering models, data on environmental releases, exposure estimates, quantitative structure activity relationship data, and environmental studies. The proposed definitions of ''data'' and ''models'' are discussed more fully in Section III.B of this preamble.

In addition, EPA is clarifying that the use of the terms ''model assumptions'' and ''models'' in the proposed regulatory text at 40 CFR 30.6 apply to the assumptions that drive the model's analytic results, not to each model assumption used in the model. EPA has modified the regulatory text at 40 CFR 30.6 to reflect this clarification.

EPA requests comment on the applicability of proposed 40 CFR 30.3, 30.5, 30.6 and 30.9 to data and models.

III. Definitions

A. ''Reanalyze'' and ''Independent Validation''

To improve the clarity of the proposed requirements, EPA is proposing definitions for certain terms.

In the 2018 proposed rulemaking, EPA used the terms ''replicate'' and ''reproducible'' and related terms. ''Replicate'' is used in the proposed regulatory text at 40 CFR 30.5. That section reads, in pertinent part, ''[I]nformation is considered 'publicly available in a manner sufficient for independent validation' when it includes the information necessary for the public to understand, assess, and replicate findings . . .'' ''Replication'' and ''reproducibility'' are both used in the 2018 proposed rulemaking preamble though neither is defined. Neither ''reproducibility'' nor its cognates are used in the regulatory text. ''Replicate'' was used but not defined in the regulatory text and its meaning was not discussed in the preamble.

Commenters contended that EPA was not clear about what it meant by the term ''replicate'' and that EPA appears to have conflated the term with ''reproducible.'' Commenters interpreted the term ''replicate'' in several different ways. For example, some commenters contended that EPA used the term ''replicate'' but actually meant ''reanalyze.'' EPA finds that these comments have merit and has determined that the intent of the term ''replicate'' should be clarified by establishing a regulatory definition.

EPA has considered the definitions in the National Academy of Sciences (NAS) ''*Principles and Obstacles for Sharing Data from Environmental Health Research.*'' (Ref. 6, NAS Workshop Report), Pellizzari, et al. ''*Reproducibility: A Primer on Semantics and Implications for Research*'' (Ref. 7), and Goodman, et al. ''*What does research reproducibility mean?*'' (Ref. 8). As demonstrated by these documents, there are varying definitions and understandings of these terms in the scientific community. Several commenters pointed to the use of the terms in the NAS Workshop Report (Ref. 6). The definitions in the NAS Workshop Report (Ref. 6) define ''reanalysis,'' ''replication,'' and ''reproduce'' as follows:

> A reanalysis is when you conduct a further analysis of data. A person doing a reanalysis of data may use the same programs and statistical methodologies that were originally used to analyze the data or may use alternative methodologies, but the point is to analyze exactly the same data to see if the same result emerges from the analysis.
>
> Replication means that you actually repeat a scientific experiment or a trial to obtain a consistent result. The second experiment uses exactly the same protocols and statistical programs but with different data from a different population. The goal is to see if the same results hold with data from a different population.
>
> When you reproduce, you are producing something that is very similar to that research, but it is in a different medium or context. In other words, a researcher who is reproducing an experiment addresses the same research question but from a different angle than the original researcher did.

EPA's use of ''replicate'' in the proposed regulatory text at 40 CFR 30.5 in the 2018 proposed rulemaking is generally consistent with the NAS Workshop Report (Ref. 6) definition of ''reanalysis.'' However, as illustrated by Refs. 4–6, and in the public comments EPA received on the 2018 proposed rulemaking, these terms are not consistently used or defined in the scientific literature. EPA now proposes to use the term ''reanalyze'' instead of ''replicate'' in 40 CFR 30.5 and is clarifying the intent of the proposed regulation by proposing a definition of ''reanalyze'' at proposed 40 CFR 30.2 as ''to analyze exactly the same data to see if the same result emerges from the analysis by using the same or different programs and statistical methodologies that were originally used to analyze the data.'' In addition to identifying potential analytical errors in the original work, reanalyzing the data would allow assessment of the robustness of the original analysis and conclusions by, for instance, showing the variability that can occur when a previously omitted variable is added to the statistical model, different functional form assumptions are made (*e.g.,* a linear marginal effect of treatment), or different assumptions are made when estimating standard errors and drawing statistical inferences (*e.g.,* allowing for spatial correlation in error terms).

In the 2018 proposed rulemaking, EPA did not define ''independent validation.'' The definition of ''independent validation'' depends on how the term ''reanalyze'' is defined. Independent validation for a scientific study that is being repeated by conducting a second scientific study would be different than independent validation where the data underlying a study is being reanalyzed to determine if the same results can be obtained. Thus, consistent with the proposed definition of ''reanalyze'' at proposed 40 CFR 30.2, EPA is proposing to define ''independent validation'' as the reanalysis of study data by subject matter experts who have not contributed to the development of the original study to demonstrate that the same analytic results are capable of being substantially reproduced. ''Capable of being substantially reproduced'' means that independent analysis of the original or supporting data using identical methods would generate similar analytic results, subject to an acceptable degree of imprecision or error.

EPA's interpretation of ''capable of being substantially reproduced'' as

included in the proposed definition above builds on the description in the ''*Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies*'' (Ref. 9). These guidelines, which were issued by the Office of Management and Budget, are intended to help agencies ensure and maximize the quality, utility, objectivity and integrity of the information that they disseminate.

EPA is requesting comment on the proposed definitions of ''reanalyze'' and ''independent validation'' at proposed 40 CFR 30.2.

B. Data and Models

Given the use of the term ''data and models'' in proposed 40 CFR 30.3, 30.5, 30.6 and 30.9 as described in Section II of this preamble, EPA is proposing to define ''data'' and ''models'' at proposed 40 CFR 30.2. EPA proposes to broaden the scope of the proposal by deleting the modifying term ''dose-response,'' as indicated above, so as to extend the reference to data and models underlying pivotal regulatory science and pivotal science used to support significant regulatory decisions and influential scientific information, respectively, not simply dose-response data and dose-response models. Examples of information that would be considered to be data and models for purposes of the proposed rulemaking include environmental fate studies, bioaccumulation data, water-solubility studies, environmental fate models, engineering models, data on environmental releases, exposure estimates, quantitative structure activity relationship data, and environmental studies. This list is not exhaustive but is intended to provide examples of the range of information that would be considered to be within the scope of data and models.

1. *Data and research data.* Data has been defined to mean, in part, the recorded factual material commonly accepted in the scientific community as necessary to validate research findings (Ref. 10). As noted by public commenters and in the NAS Workshop Report (Ref. 6), there are different stages of these data. ''There are raw data, which come straight from the survey or the experiment. There are cleaned-up data, which consist of the raw data modified to remove obvious errors.'' (These are the data that are ready to be analyzed to extract relevant information.) ''There are processed data, which are data that have been computed and analyzed to extract relevant information. There is the final clean data set that is provided with a publication. And there are the metadata that describe the data'' (Ref. 6). These different data sets or stages of data may be used for different purposes and in different contexts.

The Agency received comment asking EPA to clarify what stage of data would need to be publicly available to allow for independent validation. Thus, EPA is incorporating the concept of stage of data with the basic concept of research data as ''recorded factual material commonly accepted in the scientific community as necessary to validate research findings'' from its definition at 2 CFR 200.315. For purposes of independent validation through reanalysis, the stage of data would be the cleaned-up or analyzable data set in which obvious errors have been removed. Obvious errors do not include data that could be characterized as outliers. These data are the cleaned-up or analyzable data set (Ref. 6). Therefore, EPA is proposing to define ''data'' as the set of recorded factual material commonly accepted in the scientific community as necessary to validate research findings in which obvious errors, such as keystroke or coding errors, have been removed and that is capable of being analyzed by either the original researcher or an independent party. EPA requests comment on this proposed definition and whether the definition of ''data'' should apply to another stage of data described in Ref. 6. The focus on this later stage of data is consistent with the Federal Government's approach to data access, and specifically to EPA's ''*2016 Plan to Increase Access to Results of EPA-Funded Scientific Research*'' (Ref. 11). Finally, EPA requests comment on whether there is another definition of ''data'' that should be considered.

EPA is deleting the 2018 proposed 40 CFR 30.2 definition of ''research data,'' because this definition excludes ''trade secrets, commercial information, materials necessary to be held confidential by a researcher until they are published, or similar information which is protected under law'' and ''[p]ersonnel and medical information and similar information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, such as information that could be used to identify a particular person in a research study.'' These types of data are intended to be subject to this rulemaking. To conform with this change, EPA is deleting the 2018 proposed 40 CFR 30.10 regulatory text because it would require EPA implementation of this rulemaking to be consistent with the definition of ''research data.''

2. *Model.* EPA is proposing to define ''model'' as it is defined in EPA's *Guidance on the Development, Evaluation, and Application of Environmental Model*s (Ref. 12). EPA's guidance document was produced to aid in strengthening the Agency's development, evaluation and use of models. In this guidance document, a model is described as ''a simplification of reality that is constructed to gain insights into select attributes of a physical, biological, economic, or social system. A formal representation is characterized as the behavior of system processes, often in mathematical or statistical terms. The basis can also be physical or conceptual.'' This definition is based in part on the National Research Council's (NRC) 2007 report *Models in Environmental Regulatory Decision Making* (Ref. 13). As noted by the NRC, models can be of many different forms. They can be computational, physical, empirical, conceptual or a combination of one or more types. EPA is requesting comment on the proposed definition of ''model'' at proposed 40 CFR 30.2.

C. Publicly Available

In the 2018 proposed rulemaking, EPA used the term ''publicly available'' but did not define it at 40 CFR 30.2 or in the preamble to the 2018 proposed rulemaking. Given its use at 40 CFR 30.1, 30.5 and 30.9, EPA is proposing to define it. Publicly available information is often defined to mean information that is made available to the general public (*e.g.,* see 40 CFR 2.201, 17 CFR 160.3, 16 CFR 313.3). EPA is proposing to define it similarly to how it is defined at 16 CFR 313.3. Although the overall purpose of the regulations at 16 CFR 313 is different than the purpose of this rulemaking, the meaning of information that is available to the general public should not vary. This would encompass information legally available from government sources, the media and the internet. EPA is requesting comment on the proposed definition of ''publicly available'' at proposed 40 CFR 30.2.

IV. Availability of Data and Models

In the 2018 proposed rulemaking, EPA proposed to require at 40 CFR 30.5 that ''[w]hen promulgating significant regulatory decisions, the Agency shall ensure that dose-response data and models underlying pivotal regulatory science are publicly available in a manner sufficient for independent validation.'' EPA received a large number of comments stating that the approach in the 2018 proposed rulemaking would likely preclude the use of valid data and models from

consideration as pivotal regulatory science, because the proposed requirement to make data and models publicly available in a manner sufficient for independent validation would prevent the use of data and models that include CBI data, proprietary data, PII data that cannot be sufficiently de-identified to protect the data subjects, as well as many older studies. While having these data and models publicly available provides the greatest transparency, these commenters expressed concern that this approach could limit the use of certain data and models in EPA's significant regulatory decisions. Based on a consideration of these comments, EPA is proposing a modified version of the 2018 proposed rulemaking regulatory text at 40 CFR 30.5. Proposed 40 CFR 30.5 would allow Agency consideration of studies where there is tiered access to data and models that have CBI, proprietary data, or PII that cannot be sufficiently de-identified to protect the data subjects. For all other studies, data and models should be publicly available if the studies are to be used as pivotal regulatory science or pivotal science.

As discussed in OMB M–19–15 (Ref. 3), risk reduction techniques include creating multiple versions of a single dataset with varying levels of specificity and protection. The benefit of tiered access is that data users who wish to conduct activities with a statistical purpose without first obtaining special authorization have access to the versions of the data in the least restricted tiers, allowing them to conduct research while protecting confidentiality.

EPA is also proposing an alternative approach to today's proposed 40 CFR 30.5. Under alternative proposed 40 CFR 30.5, when promulgating significant regulatory decisions or finalizing influential scientific information, the Agency will, other things equal, give greater consideration to studies where the underlying data and models are available in a manner sufficient for independent validation either because the information is publicly available or available through tiered access when the data include CBI, proprietary data, or PII and appropriate techniques have been used to reduce the risk of re-identification. In developing the significant regulatory decision or influential scientific information, the EPA will identify those studies that are given greater consideration and provide a short description of why greater consideration was given. However, the Agency may still consider studies where there is no access or limited access to underlying data and models.

EPA is also clarifying that the Agency does not intend to make all data and models underlying pivotal regulatory science and pivotal science publicly available. There may be instances where EPA does not own the data and models, lacks access to part or all of the data and models or does not have the authority to provide access to part or all of the data and models. Rather, EPA is describing how it will handle studies based on whether the underlying data and models are publicly available.

Both today's proposal and alternate proposal are consistent with EPA's statements in the April 2018 proposed rulemaking that ''access to dose response data and models underlying pivotal regulatory science'' should be done ''in a manner consistent with statutory requirements for protection of privacy and confidentiality of research participants, protection of proprietary data and confidential business information, and other compelling interests'' (Ref. 1). Both approaches are also based on EPA's recognition that there are statutory restrictions to public availability for some data and models that could make independent validation difficult. Further, both of these approaches are consistent with the OMB's M–19–15 (Ref. 3). OMB's implementation updates direct federal agencies to ''explore methods that provide wider access to datasets while reducing the risk of disclosure of [PII]. . .[T]iered access offers promising ways to make data widely available while protecting privacy'' (Implementation Update 3.5, Ref. 3). In addition, ''Agencies should prioritize increased access to the data and analytic frameworks (*e.g.,* models) used to generate influential information'' while being ''consistent with statutory, regulatory, and policy requirements for protections of privacy and confidentiality, proprietary data, and confidential business information'' (Implementation Update 3.4, Ref. 3). This proposal is also consistent with OMB *Memorandum 13–13: Open Data Policy—Managing Information as an Asset* (Ref. 14).

Under a tiered approach to accessing data and models that include CBI, proprietary data, or PII that cannot be sufficiently de-identified to protect the data subjects, access is more restricted for more sensitive data and models. Thus, the amount of information available for analysis is dictated by the tier. The greatest amount of information is made available at the most restricted access tier. Access to data involving PII would be consistent with the requirements of the Common Rule, the Health Insurance Portability and Accountability Act (HIPPA), the 21st Century Cures Act, the Privacy Act, and other relevant laws and regulations, and EPA privacy policies. Reanalyzing findings of studies based on data and models that include PII (*e.g.,* residence) or CBI may not be possible given the degree of perturbation caused by de-identification that would be needed for the information to be made publicly available. Restricted access for researchers through secure data enclaves for PII or through non-disclosure agreements for CBI may result in access to sufficient information about the data and models to allow for independent validation. This ability to reanalyze findings may be much more limited for less restricted tiers. Thus, reanalysis of findings for some data and models may be limited to authorized researchers and not possible for the general public.

A model of tiered access for data involving PII is the Research Data Center (RDC), National Center for Health Statistics (NCHS), Centers for Disease Control (CDC). The NCHS operates the RDC to allow researchers access to restricted-use data. The RDC provides access to the restricted-use data while protecting the confidentiality of survey respondents, study subjects, or institutions. For access to the restricted-use data, researchers must submit a research proposal outlining the need for restricted-use data. The submitted research proposal is intended to provide a framework for NCHS to identify potential disclosure risks and how the data will be used (Ref. 15). EPA is currently conducting a pilot study using the RDC's secure data enclave to host EPA datasets in a restricted use environment.

Development of standard data repositories is still ongoing. For example, the White House Office of Science and Technology Policy recently solicited public comments on a draft set of characteristics of data repositories used to locate, manage, share, and use data resulting from federally-funded research (85 FR 3085). The effort is intended to help federal agencies provide more consistent information on desirable characteristics of data repositories ''for data subject to agency Public Access Plans and data management and sharing policies, whether those repositories are operated by government or nongovernmental entities.'' Information received during this public comment period will, among other things, help inform improved guidance and best practices related to preserving and providing access to data.

Access to CBI data would continue to be provided consistent with the

environmental statutes EPA implements and the regulations at 40 CFR part 2, subpart B, which govern CBI. These regulations establish basic rules governing business confidentiality claims, how EPA handles business information that is or may be entitled to confidential treatment, and how EPA determines whether information is entitled to confidential treatment for reasons of business confidentiality. Various statutes under which EPA operates contain special provisions concerning the entitlement to confidential treatment of information gathered under such statutes. The regulations at 40 CFR part 2 subpart B prescribe rules for treating certain categories of business information obtained under the various statutory provisions.

In accordance with these statutes, both the proposed and alternative 40 CFR 30.5 provide that access to underlying data and models that include CBI, proprietary information, or PII, for the subset of studies that could be considered pivotal science, may be limited to authorized officials and researchers and not provided to the general public.

Proposed 40 CFR 30.5 would maintain the temporal approach to data and models taken in the regulatory text of 40 CFR 30.5 of the 2018 proposed rulemaking, and thus would apply to data and models evaluated at the time a significant regulatory action or influential scientific information is developed, regardless of when the data and models were generated. EPA is requesting comment on whether this should apply only to data and models that are generated (*i.e.,* when the development of the data set or model has been completed or updated) after the effective date of this rulemaking. If the proposed or alternative approach were finalized, EPA would consider the availability of underlying data and models only for studies that are potentially pivotal to EPA's significant regulatory decisions or influential scientific information that are developed in the future.

Although the ability to independently validate pivotal regulatory science or pivotal science is a key component of this rulemaking, EPA would like to clarify that neither the proposed nor the alternative 40 CFR 30.5 would require that EPA, a member of the public or other entity must independently validate a study before it can be considered to be pivotal regulatory science or pivotal science. EPA would also like to clarify that independent validation is not required under proposed 40 CFR 30.7 which describes the role of independent peer review.

EPA is requesting comment on the regulatory text being proposed today for 40 CFR 30.5. For alternate proposed 40 CFR 30.5, EPA is also requesting comment on how much consideration should be given to studies when there is limited or no access to the underlying data and models. In addition, EPA is requesting comment on how to ensure that, over time, more of the data and models underlying the science that informs significant regulatory decisions and influential scientific information are available to the public for independent validation in a manner that honors legal and ethical obligations to reduce the risks of unauthorized disclosure and re-identification. Finally, EPA is interested in comments about how to provide sufficient incentives and support to researchers to increase access to the data that may be used as pivotal regulatory science or pivotal science. Such comments will be used to develop implementation guidance.

V. Exemption by the Administrator

The 2018 proposed rulemaking includes a provision at 40 CFR 30.9 allowing the Administrator to grant exemptions from the rule on a case-by-case basis if he or she determines that compliance is impracticable because it is not feasible to ensure that data and models underlying pivotal regulatory science are publicly available in a manner that is consistent with law and protects privacy and confidentiality. EPA is clarifying that the exemption may be given if compliance is impracticable because technological barriers render sharing of the data or models infeasible.

EPA is also modifying the scope of the data and models that can be considered when determining whether to grant an exemption. The underlying data, models and computer code for some studies, particularly older studies, may not be readily publicly available because of the technological barriers to data and model sharing (*e.g.,* differences in data storage devices or data retention practices) that existed when they were developed. Thus, in 40 CFR 30.9(a), EPA is proposing to use the age of data and models as a factor in the determination that compliance with the rule is impracticable. This modification of scope is intended to acknowledge the evolution of best practices for information sharing given innovations in information generation, access, management and use (See Ref. 3). EPA is proposing that a study or studies would be eligible for consideration under 40 CFR 30.9(a), regardless of whether they contain CBI, proprietary information, or PII, if the underlying data or models were collected, completed or updated before the effective date of this rule. EPA requests comment on this consideration of the age of data and models in determining the feasibility of making underlying data and models publicly available. EPA also requests comment on whether there are aspects other than the year the data or model was collected, completed or updated that EPA should consider in determining whether to grant an exemption in order to evaluate the technological barriers to sharing.

The 2018 proposed rulemaking also included a provision at 40 CFR 30.9 allowing the Administrator to grant exemptions from the rule on a case-by-case basis if he or she determines that compliance is impracticable because it is not feasible to conduct independent peer review on all pivotal regulatory science. EPA is deleting that provision of the proposed exemption because EPA does not believe that peer review of pivotal regulatory science or pivotal science would be infeasible. Thus, EPA no longer believes the provision is necessary.

VI. References

The following is a listing of the documents that are specifically referenced in this notice. The docket includes these documents and other information considered by EPA, including documents referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. Strengthening Transparency in Regulatory Science; Proposed Rule. **Federal Register** (83 FR18768, April 30, 2018) (FRL–9977–40).

2. EPA. Strengthening Transparency in Regulatory Science; Extension of Comment Period and Notice of Public Hearing **Federal Register** (83 FR. 24255, May 25, 2018).

3. OMB (Office of Management and Budget). (2019). Improving Implementation of the Information Quality Act. Memorandum for the Heads of Executive Departments and Agencies. OMB Issuance M–19–15. Washington, DC: Executive Office of the President. *https://www.whitehouse.gov/wp-content/uploads/2019/04/M-19-15.pdf.*

4. OMB (Office of Management and Budget). (2004). Memorandum for the Heads of Executive Departments and Agencies on Final Information Quality Bulletin for Peer-Review. *https://obamawhitehouse.archives.gov/sites/default/files/omb/assets/omb/memoranda/fy2005/m05-03.pdf.*

5. OMB (Office of Management and Budget). (2019). Executive Order 13891 of

October 9, 2019. Promoting the Rule of Law Through Improved Agency Guidance Documents. 84 FR 199. *https://www.govinfo.gov/content/pkg/FR-2019-10-15/pdf/2019-22623.pdf.*

6. NAS (National Academies of Sciences, Engineering, and Medicine). (2016). Principles and obstacles for sharing data from environmental health research: Workshop summary. Washington, DC: The National Academies Press. *https://doi.org/10.17226/21703.*

7. Pellizzari, YE; Lohr, K, Blatecky, A.; Creel, D. (2017). Reproducibility: A Primer on Semantics and Implications for Research. Research Triangle Park, NC: RTI Press.

8. Goodman, SN; Fanelli, D; Ioannidis, JPA. (2016). What does research reproducibility mean? Sci Translational Medicine 8: 341ps12. *https://doi.org/10.1126/scitranslmed.aaf5027.*

9. OMB (Office of Management and Budget). (2002). Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Final guidelines. 67 FR 8452–8460. *https://www.govinfo.gov/content/pkg/FR-2002-02-22/pdf/R2-59.pdf.*

10. OMB (Office of Management and Budget). (2013). Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards; Final Rule. 78 FR 78589–78691. *https://www.govinfo.gov/content/pkg/FR-2013-12-26/pdf/2013-30465.pdf.*

11.U.S. EPA (U.S. Environmental Protection Agency).(2016). Plan to Increase Access to Results of EPA-Funded Scientific Research. (EPA/601–R–16–005). Washington, DC: U.S. Environmental Protection Agency. *https://www.epa.gov/sites/production/files/2016-12/documents/epascientific researchtransperancyplan.pdf.*

12. U.S. EPA (U.S. Environmental Protection Agency). (2009). Guidance on the Development, Evaluations, and Application of Environmental Models. (EPA/100/K–09/003). Washington, DC: US. Environmental Protection Agency. *https://www.epa.gov/sites/production/files/2015-04/documents/cred_guidance_0309.pdf.*

13. NRC (National Research Council). (2007). Models in Environmental Regulatory Decision Making. Washington, DC: The National Academies Press. *https://doi.org/10.17226/11972.*

14. OMB (Office of Management and Budget). (2013). Memorandum for the Heads of Executive Departments and Agencies on Open Data Policy-Managing Information as an Asset (*https://projectopen-data.cio.gov/policy-memo/*).

15. CDC (Centers for Disease Control). Research Data Center. *https://www.cdc.gov/rdc/index.htm.*

VII. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review. Any changes made in response to OMB recommendations have been documented in the docket.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is not expected to be an Executive Order 13771 regulatory action because it relates to ''agency organization, management or personnel.''

C. Paperwork Reduction Act (PRA)

This action does not contain any information collection activities and therefore does not impose an information collection burden under the PRA.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities. This action does not regulate any entity outside the federal government.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

F. Executive Order 13132: Federalism

This action does not have federalism implications. It will not 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.

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this action.

H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

I. Executive Order 13211: Actions Concerning Regulations 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.

J. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this action is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994) because it does not establish an environmental health or safety standard.

List of Subjects in 40 CFR Part 30

Environmental protection, Administrative practice and procedure, Reporting and recordkeeping requirements.

Dated: March 3, 2020.

Andrew R. Wheeler,

Administrator.

Therefore, 40 CFR part 30, as proposed to be added at 83 FR 18768 (April 30, 2018), is proposed to be amended as follows:

PART 30—TRANSPARENCY IN REGULATORY DECISIONMAKING

■ 1. The authority citation for part 30 is revised to read as follows:

Authority: 5 U.S.C. 301; 5 U.S.C. App.; Pub. L. 98–80, 84 Stat. 2086.

■ 2. Revise § 30.2 by adding the definitions for ''*Capable of being substantially reproduced*'', ''*Data*'', ''*Independent validation*'', ''*Influential scientific information*'' ''*Model*'', ''*Pivotal science*'', ''*Publicly available*'' and ''*Reanalyze*'' in alphabetical order to read as follows:

§ 30.2 What definitions apply to this part?

Capable of being substantially reproduced means that independent analysis of the original or supporting data using identical methods would generate similar analytic results, subject to an acceptable degree of imprecision or error.

Data means the set of recorded factual material commonly accepted in the scientific community as necessary to validate research findings in which obvious errors, such as keystroke or coding errors, have been removed and that is capable of being analyzed by either the original researcher or an independent party.

* * * * *

Independent validation means the reanalysis of study data by subject matter experts who have not contributed to the development of the study to demonstrate that the same analytic results reported in the study are capable of being substantially reproduced.

Influential scientific information means scientific information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions.

Model means a simplification of reality that is constructed to gain insights into select attributes of a physical, biological, economic, or social system. A formal representation of the behavior of system processes, often in mathematical or statistical terms. The basis can also be physical or conceptual.

* * * * *

Pivotal science means the specific scientific studies or analyses that underly influential scientific information.

Publicly available means lawfully available to the general public from federal, state, or local government records; the internet; widely distributed media; or disclosures to the general public that are required to be made by federal, state, or local law.

Reanalyze means to analyze exactly the same data to see if the same result emerges from the analysis by using the same or different statistical software, models, and statistical methodologies that were originally used to analyze the data, as well as to assess potential analytical errors and variability in the underlying assumptions of the original analysis.

* * * * *

■ 3. Revise § 30.3 to read as follows:

§ 30.3 How do the provisions of this part apply?

The provisions of this part apply to data and models, underlying pivotal science supporting influential scientific information and/or underlying pivotal regulatory science used to justify significant regulatory decisions regardless of the source of funding or identity of the party conducting the science. The provisions of this section do not apply to physical objects (like laboratory samples), drafts, and preliminary analyses. In the event the procedures outlined in this part conflict with statutes that EPA administers, or their implementing regulations, the statutes and regulations will control. Except where explicitly stated otherwise, the provisions of this part do not apply to any other type of agency action, including individual party adjudications, enforcement activities, or permit proceedings.

[Option 1]

■ 4. Revise § 30.5 to read as follows:

§ 30.5 What requirements apply to EPA's use of data and models underlying pivotal regulatory science and pivotal science?

When promulgating significant regulatory decisions or finalizing influential scientific information, the Agency will only use pivotal regulatory science and/or pivotal science that includes studies with restricted data and models (*i.e.,* those that include confidential business information (CBI), proprietary data, or Personally Identifiable Information (PII) that cannot be sufficiently de-identified to protect the data subjects) if there is tiered access to these data and models in a manner sufficient for independent validation, and studies that do not include restricted data and models if the data and models are publicly available in a manner sufficient for independent validation. Where the Agency is making data or models publicly available, it shall do so in a manner that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security. Information is considered ''available in a manner sufficient for independent validation'' when it includes the information necessary to understand, assess, and reanalyze findings. This may include, for example:

(a) Data (where necessary, data would be made available subject to access and use restrictions);

(b) Associated protocols necessary to understand, assess, and extend conclusions;

(c) Computer codes and models involved in the creation and analysis of such information;

(d) Recorded factual materials; and

(e) Detailed descriptions of how to access and use such information.

(f) The provisions of this section apply to data and models underlying pivotal regulatory science or pivotal science regardless of who funded or conducted the underlying data, models, or other regulatory science or pivotal science. The agency shall make reasonable efforts to explore methodologies, technologies, and institutional arrangements for making such data and models available before it concludes that doing so in a manner consistent with law and protection of privacy, confidentiality, national and homeland security is not possible. Where data and models are controlled by third parties, EPA may work with those parties to endeavor to make the data and models available in a manner that complies with this section.

[Option 2]

■ 5. Revise § 30.5 to read as follows:

§ 30.5 What requirements apply to EPA's use of data and models underlying pivotal regulatory science and pivotal science?

(a) When promulgating significant regulatory decisions or finalizing influential scientific information, the Agency will, other things equal, give greater consideration to studies where the underlying data and models are publicly available in a manner sufficient for independent validation. The Agency will also give greater consideration to studies based on data and models that include confidential business information, proprietary information or personally identifiable information if these data and models were available through restricted access, such as through a secure data enclave, in a manner sufficient for independent validation. Where there is no access to data and models, or access is limited, the Agency may still consider these studies, depending on the other attributes of the studies. Furthermore, the Agency will identify those studies that are given greater consideration and provide a short description of why greater consideration was given. Where the Agency is making data or models publicly available, it shall do so in a manner that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security. Information is considered ''available in a manner sufficient for independent validation'' when it includes the information necessary to understand, assess, and reanalyze findings. This may include, for example:

(1) Data (where necessary, data would be made available subject to access and use restrictions);

(2) Associated protocols necessary to understand, assess, and extend conclusions;

(3) Computer codes and models involved in the creation and analysis of such information;

(4) Recorded factual materials; and

(5) Detailed descriptions of how to access and use such information.

(b) The provisions of this section apply to data and models underlying pivotal regulatory science or pivotal science regardless of who funded or conducted the underlying data, models, or other regulatory science or pivotal science. The agency shall make reasonable efforts to explore methodologies, technologies, and institutional arrangements for making such data and models available before it concludes that doing so in a manner consistent with law and protection of privacy, confidentiality, national and homeland security is not possible. Where data and models are controlled by third parties, EPA may work with those parties to endeavor to make the data and models available in a manner that complies with this section.

■ 6. Revise § 30.6 to read as follows:

§ 30.6 What additional requirements pertain to the use of data and models underlying pivotal science or pivotal regulatory science?

EPA shall describe and document any assumptions and methods used and shall describe variability and uncertainty. EPA shall evaluate the appropriateness of using default assumptions on a case-by-case basis. EPA shall clearly explain the scientific basis for critical assumptions used in the analysis that drove the analytical results and subsequent decisions and shall present analyses showing the sensitivity of the modeled results to alternative assumptions. When available, EPA shall give explicit consideration to high quality studies, including but not limited to those that explore: A broad class of parametric dose-response or concentration-response models; a robust set of potential confounding variables; nonparametric models that incorporate fewer assumptions; various threshold models across the dose or exposure range; and models that investigate factors that might account for spatial heterogeneity.

■ 7. Revise § 30.7 to read as follows:

§ 30.7 What role does independent peer review have in this section?

EPA shall conduct independent peer review on all pivotal regulatory science used to justify significant regulatory decisions and on all pivotal science underlying influential scientific information, consistent with the requirements of the OMB Final Information Quality Bulletin for Peer Review and the exemptions described therein. Because transparency in regulatory science includes addressing issues associated with assumptions used in models, EPA shall ask peer reviewers to articulate the strengths and weaknesses of EPA's justification for the assumptions applied and the implications of those assumptions for the results.

■ 8. Revise § 30.9 to read as follows:

§ 30.9 May the EPA Administrator grant exemptions to this part?

The Administrator may grant an exemption to this part on a case-by case basis if he or she determines that compliance is impracticable because technological barriers render sharing of the data or models infeasible, the development of the data or model was completed or updated before [*EFFECTIVE DATE OF FINAL RULE*] or making the data and models publicly available would conflict with laws governing privacy, confidentiality, confidential business information, or national and homeland security.

[FR Doc. 2020–05012 Filed 3–17–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 721 and 725

[EPA–HQ–OPPT–2020–0094; FRL–10005–76]

RIN 2070–AB27

Significant New Use Rules on Certain Chemical Substances (20–3.B)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for chemical substances which are the subject of premanufacture notices (PMNs) and a microorganism that was the subject of a Microbial Commercial Activity Notice (MCAN). This action would require persons to notify EPA at least 90 days before commencing manufacture (defined by statute to include import) or processing of any of these chemical substances for an activity that is designated as a significant new use by this proposed rule. This action would further require that persons not commence manufacture or processing for the significant new use until they have submitted a Significant New Use Notice, and EPA has conducted a review of the notice, made an appropriate determination on the notice under TSCA, and has taken any risk management actions as are required as a result of that determination.

DATES: Comments must be received on or before April 17, 2020.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2020–0094, 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 Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 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.*

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Kenneth Moss, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–9232; email address: *moss.kenneth@epa.gov.*

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you manufacture, process, or use the chemical substances contained in this proposed rule. 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:

• Manufacturers or processors of one or more subject chemical substances (NAICS codes 325 and 324110), *e.g.,* chemical manufacturing and petroleum refineries.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements promulgated at 19 CFR 12.118 through 12.127 and 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. Importers of chemicals subject to these proposed SNURs would need to certify their compliance with the SNUR requirements should these proposed rules be finalized. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, pursuant to 40 CFR 721.20 or 725.920 for the MCAN substance, any persons who export or intend to export a chemical substance that is the subject of this proposed rule on or after April 17, 2020 are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) must comply with the export notification requirements in 40 CFR part 707, subpart D.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit CBI to EPA through 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.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html.*

II. Background

A. What action is the Agency taking?

EPA is proposing these SNURs under TSCA section 5(a)(2) for chemical substances which were the subjects of MCAN J–19–1 and PMNs P–18–391 and P–20–13. These proposed SNURs would require persons who intend to manufacture or process any of these chemical substances for an activity that is designated as a significant new use to notify EPA at least 90 days before commencing that activity.

The record for the proposed SNURs on these chemicals was established as docket ID number EPA–HQ–OPPT–2020–0094. That record includes information considered by the Agency in developing these proposed SNURs.

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

TSCA section 5(a)(2) (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a ''significant new use.'' EPA must make this determination by rule after considering all relevant factors, including the four TSCA section 5(a)(2) factors listed in Unit III. In the case of a determination other than not likely to present unreasonable risk, the applicable review period must also expire before manufacturing or processing for the new use may commence.

C. Applicability of General Provisions

General provisions for SNURs appear in 40 CFR part 721, subpart A and (for microorganisms) 40 CFR part 725, subpart L. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the rule. Provisions relating to user fees appear at 40 CFR part 700. Pursuant to 40 CFR 721.1(c), persons subject to these SNURs must comply with the same SNUN requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A) (15 U.S.C. 2604(a)(1)(A)). In particular, these requirements include the information submission requirements of TSCA sections 5(b) and 5(d)(1) (15 U.S.C. 2604(b) and 2604(d)(1)), the exemptions authorized by TSCA sections 5(h)(1), 5(h)(2), 5(h)(3), and 5(h)(5) and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA must either determine that the use is not likely to present an unreasonable risk of injury under the conditions of use for the chemical substance or take such regulatory action as is associated with an alternative determination before the manufacture or processing for the significant new use can commence. If EPA determines that the use is not likely to present an unreasonable risk, EPA is required under TSCA section 5(g) to make public, and submit for publication in the **Federal Register**, a statement of EPA's findings.

III. Significant New Use Determination

TSCA section 5(a)(2) states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors, including:

• The projected volume of manufacturing and processing of a chemical substance.

• The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.

• The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.

• The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In determining what would constitute a significant new use for the chemical substances that are the subject of these SNURs, EPA considered relevant information about the toxicity of the chemical substances, and potential human exposures and environmental releases that may be associated with the conditions of use of the substances, in the context of the four bulleted TSCA section 5(a)(2) factors listed in this unit. During its review of these chemicals, EPA identified certain conditions of use that are not intended by the submitters, but reasonably foreseen to occur. EPA is proposing to designate those reasonably foreseen conditions of use as significant new uses.

IV. Substances Subject to This Proposed Rule

EPA is proposing significant new use and recordkeeping requirements for two chemical substances in 40 CFR part 721, subpart E and one chemical substance that is a microorganism in MCAN J–19–1 in 40 CFR part 725. In this unit, EPA provides the following information for each chemical substance:

• PMN or number.

• Chemical name (generic name, if the specific name is claimed as CBI).

• Chemical Abstracts Service (CAS) Registry number (if assigned for non-confidential chemical identities).

• Basis for the SNUR.

• Potentially Useful Information. This is information identified by EPA that would help characterize the potential health and/or environmental effects of the chemical substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a

SNUN for a significant new use designated by the SNUR.

• CFR citation assigned in the regulatory text section of these proposed rules.

The regulatory text section of these proposed rules specifies the activities designated as significant new uses. Certain new uses, including production volume limits and other uses designated in the proposed rules, may be claimed as CBI.

The chemical substances that are the subject of these proposed SNURs are undergoing premanufacture review. In addition to those conditions of use intended by the submitter, EPA has identified certain other reasonably foreseen conditions of use. EPA has preliminarily determined that the chemicals under their intended conditions of use are not likely to present an unreasonable risk. However, EPA has not assessed risks associated with the reasonably foreseen conditions of use for these chemicals. EPA is proposing to designate these reasonably foreseen and other potential conditions of use as significant new uses. As a result, those conditions of use are no longer reasonably foreseen to occur without first going through a separate, subsequent EPA review and determination process associated with a SNUN.

The substances subject to these proposed rules are as follows:

PMN Number: P–18–391

Chemical name: 1-Propanaminium, N-(carboxymethyl)-N, N-dimethyl-3-[(3,5, 5-trimethyl-1-oxohexyl), amino]-inner salt.

CAS number: 2169783–63–3.

Basis for action: The PMN states that the use of the substance will be in liquid laundry detergent. Based on the physical/chemical properties of the PMN substance, test data on the PMN substance and SAR analysis of test data on analogous substances, EPA has identified concerns for lung effects (lung surfactancy), systemic (maternal) and developmental effects, and irritation to skin and eyes if the chemical substance is used in ways other than as intended by the PMN submitter. Other conditions of use of the PMN substance that EPA intends to assess before they occur include the following:

• It is a significant new use to manufacture, process, or use the substance for any use that results in inhalation exposures.

The proposed SNUR would designate as a ''significant new use'' these conditions of use.

Potentially useful information: EPA has determined that certain information may be potentially useful to characterize the health effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of specific target organ toxicity would help characterize the potential health effects of the PMN substance.

CFR citation: 40 CFR 721. 11460.

PMN Number: P–20–13

Chemical name: 2-Propenoic acid, 2-methyl-, (2-oxo-1,3-dioxolan-4-yl)methyl ester.

CAS number: 13818–44–5.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be in UV curable inks. Based on the physical/chemical properties of the PMN substance and SAR analysis of test data on analogous substances, EPA has identified concerns for respiratory sensitization, eye irritation, systemic toxicity, neurotoxicity, reproductive and developmental toxicity, immunotoxicity, liver and kidney effects if the chemical substance is used in ways other than as intended by the PMN submitter. Other conditions of use of the PMN substance that EPA intends to assess before they occur include the following:

• Annual manufacture (including import) volume greater than the confidential amount identified in the PMN;

• Use other than the confidential use described in the PMN; and

• Use in a consumer product.

The proposed SNUR would designate as a ''significant new use'' these conditions of use.

Potentially useful information: EPA has determined that certain information may be potentially useful to characterize the health effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of respiratory sensitization, specific target organ toxicity, neurotoxicity, and reproductive toxicity (developmental effects) testing would help characterize the potential health effects of the PMN substance.

CFR citation: 40 CFR 721. 11461.

MCAN Number: J–19–1

Chemical name: Trichoderma reesei strain 3CH–3.

CAS number: Not available.

Basis for action: The MCAN states that the use of the substance will be to induce the production of biomass-degrading cellulases used for the manufacture of sugars or sugar-derived substances. EPA determined that certain fermentation conditions, other than the typical submerged standard industrial fermentation process for enzyme production, could result in increased exposures. Specifically, EPA is concerned that where growth on plant material or on solid substrates occurs, *T. reesei* has been shown to produce a secondary metabolite known as paracelsin, which is associated with a variety of toxic effects to mammalian and bacterial cells. The intended conditions of use of the MCAN microorganism described in the MCAN include the following protective measures:

• No manufacture, processing, or use of the microorganism other than in a fermentation system that meets all of the following conditions:

(A) Enzyme production occurs by submerged fermentation (*i.e.,* for enzyme production, growth of the microorganism occurs beneath the surface of the liquid growth medium);

(B) Any fermentation of solid plant material or insoluble substrate, to which *Trichoderma reesei* fermentation broth is added after the standard industrial fermentation is completed, is initiated only after the inactivation of the microorganism as delineated in 40 CFR 725.422(d).

The proposed SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information: EPA has determined that the results of the following studies would help characterize any potential human health and environmental effects of the MCAN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this SNUR:

• Investigation of whether paracelsin will be produced, and at what levels if the genetically-modified *T. reesei* is grown on various plant biomass materials for different durations under various fermentation conditions in cellulosic biomass facilities.

• If paracelsin is produced, a study of whether paracelsin would be denatured/inactivated during production and processing.

• If paracelsin is released from the facility, a study of whether paracelsin would be degraded/inactivated during wastewater treatment.

• If released to the environment, studies on the persistence, stability, dissemination, accumulation, and the potential resulting biological activity of paracelsin with exposure to aquatic and

terrestrial organisms in the environment.

• Studies to determine the ability of the MCAN microorganism to survive in the environment relative to the survival of the unmodified parent or recipient strain, and to assess its competitiveness with other fungi in the environment. This study may require some supplementation with one or more carbon sources and the use of various soil types.

• A study to determine survival of the fungus during an anaerobic fermentation for production of ethanol by an ethanologen, and survival of the fungus during ethanol distillation or at the distillation temperature for ethanol.

CFR citation: 40 CFR 725.1080.

V. Rationale and Objectives of the Proposed Rule

A. Rationale

During review of the PMNs submitted for the chemical substances that are the subject of these proposed SNURs and as further discussed in Unit IV, EPA identified certain other reasonably foreseen conditions of use, in addition to those conditions of use intended by the submitter. EPA has preliminarily determined that the chemical under the intended conditions of use is not likely to present an unreasonable risk. However, EPA has not assessed risks associated with the reasonably foreseen conditions of use. EPA is proposing to designate these conditions of use as significant new uses to ensure that they are no longer reasonably foreseen to occur without first going through a separate, subsequent EPA review and determination process associated with a SNUN.

B. Objectives

EPA is proposing these SNURs because the Agency wants:

• To have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing or processing a listed chemical substance for the described significant new use.

• To be obligated to make a determination under TSCA section 5(a)(3) regarding the use described in the SNUN, under the conditions of use. The Agency will either determine under TSCA section 5(a)(3)(C) that the significant new use is not likely to present an unreasonable risk, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, or make a determination under TSCA section 5(a)(3)(A) or (B) and take the required regulatory action associated with the determination, before manufacture or processing for the significant new use of the chemical substance can occur.

• To be able to complete its review and determination on each of the PMN or MCAN substances, while deferring analysis on the significant new uses proposed in these rules unless and until the Agency receives a SNUN.

Issuance of a proposed SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Inventory. Guidance on how to determine if a chemical substance is on the TSCA Inventory is available on the internet at *https://www.epa.gov/tsca-inventory.*

VI. Applicability of the Proposed Rules to Uses Occurring Before the Effective Date of the Final Rule

To establish a significant new use, EPA must determine that the use is not ongoing. The chemical substances subject to this proposed rule were undergoing premanufacture review at the time of signature of this proposed rule and were not on the TSCA Inventory. In cases where EPA has not received a notice of commencement (NOC) and the chemical substance has not been added to the TSCA Inventory, no person may commence such activities without first submitting a PMN. Therefore, for the chemical substances subject to these proposed SNURs, EPA concludes that the proposed significant new uses are not ongoing.

EPA designates March 4, 2020 as the cutoff date for determining whether the new use is ongoing. The objective of EPA's approach is to ensure that a person cannot defeat a SNUR by initiating a significant new use before the effective date of the final rule.

Persons who begin commercial manufacture or processing of the chemical substances for a significant new use identified on or after that date would have to cease any such activity upon the effective date of the final rule. To resume their activities, these persons would have to first comply with all applicable SNUR notification requirements and EPA would have to take action under TSCA section 5 allowing manufacture or processing to proceed. In developing this proposed rule, EPA has recognized that, given EPA's general practice of posting proposed rules on its website a week or more in advance of **Federal Register** publication, this objective could be thwarted even before **Federal Register** publication of the proposed rule.

VII. Development and Submission of Information

EPA recognizes that TSCA section 5 does not require development of any particular new information (*e.g.,* generating test data) before submission of a SNUN. There is an exception: If a person is required to submit information for a chemical substance pursuant to a rule, Order or consent agreement under TSCA section 4 (15 U.S.C. 2603), then TSCA section 5(b)(1)(A) (15 U.S.C. 2604(b)(1)(A)) requires such information to be submitted to EPA at the time of submission of the SNUN.

In the absence of a rule, Order, or consent agreement under TSCA section 4 covering the chemical substance, persons are required only to submit information in their possession or control and to describe any other information known to or reasonably ascertainable by them (see 40 CFR 720.50 and 725.155). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. Unit IV. lists potentially useful information for all SNURs listed here. Descriptions are provided for informational purposes. The potentially useful information identified in Unit IV. will be useful to EPA's evaluation in the event that someone submits a SNUN for the significant new use. Companies who are considering submitting a SNUN are encouraged, but not required, to develop the information on the substance, which may assist with EPA's analysis of the SNUN.

EPA strongly encourages persons, before performing any testing, to consult with the Agency pertaining to protocol selection. Furthermore, pursuant to TSCA section 4(h), which pertains to reduction of testing in vertebrate animals, EPA encourages consultation with the Agency on the use of alternative test methods and strategies (also called New Approach Methodologies, or NAMs), if available, to generate the recommended test data. EPA encourages dialog with Agency representatives to help determine how best the submitter can meet both the data needs and the objective of TSCA section 4(h).

The potentially useful information described in Unit IV. may not be the only means of providing information to evaluate the chemical substance associated with the significant new uses. However, submitting a SNUN without any test data may increase the likelihood that EPA will take action under TSCA section 5(e) or 5(f). EPA recommends that potential SNUN submitters contact EPA early enough so

that they will be able to conduct the appropriate tests.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs which provide detailed information on the following:

- Human exposure and environmental release that may result from the significant new use of the chemical substances.

VIII. SNUN Submissions

According to 40 CFR 721.1(c), persons submitting a SNUN must comply with the same notification requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 40 CFR 720.50 or 725.160. SNUNs must be submitted on EPA Form No. 7710–25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in 40 CFR 720.40 and 721.25 (or 40 CFR 725.25 and 725.27 for an MCAN). E–PMN software is available electronically at *https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca.*

IX. Economic Analysis

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacturers and processors of the chemical substances subject to this proposed rule. EPA's complete economic analysis is available in the docket under docket ID number EPA–HQ–OPPT–2020–0094.

X. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulations and Regulatory Review

This proposed rule would establish SNURs for new chemical substances that were the subject of PMNs. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act (PRA)

According to the PRA, 44 U.S.C. 3501 *et seq.,* an Agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable.

The information collection requirements related to this action have already been approved by OMB pursuant to PRA under OMB control number 2070–0012 (EPA ICR No. 574). This action does not impose any burden requiring additional OMB approval. If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average between 30 and 170 hours per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, to the Director, Regulatory Support Division, Office of Mission Support (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001. Please remember to include the OMB control number in any correspondence, but do not submit any completed forms to this address.

C. Regulatory Flexibility Act (RFA)

Pursuant to section 605(b) of the RFA, 5 U.S.C. 601 *et seq.,* the Agency hereby certifies that promulgation of this proposed SNUR would not have a significant adverse economic impact on a substantial number of small entities. The requirement to submit a SNUN applies to any person (including small or large entities) who intends to engage in any activity described in the final rule as a ''significant new use.'' Because these uses are ''new,'' based on all information currently available to EPA, it appears that no small or large entities presently engage in such activities. A SNUR requires that any person who intends to engage in such activity in the future must first notify EPA by submitting a SNUN. Although some small entities may decide to pursue a significant new use in the future, EPA cannot presently determine how many, if any, there may be. However, EPA's experience to date is that, in response to the promulgation of SNURs covering over 1,000 chemicals, the Agency receives only a small number of notices per year. For example, the number of SNUNs received was seven in Federal fiscal year (FY) 2013, 13 in FY2014, six in FY2015, 12 in FY2016, 13 in FY2017, and 11 in FY2018, only a fraction of these were from small businesses. In addition, the Agency currently offers relief to qualifying small businesses by reducing the SNUN submission fee from $16,000 to $2,800. This lower fee reduces the total reporting and recordkeeping of cost of submitting a SNUN to about $10,116 for qualifying small firms. Therefore, the potential economic impacts of complying with this proposed SNUR are not expected to be significant or adversely impact a substantial number of small entities. In a SNUR that published in the **Federal Register** of June 2, 1997 (62 FR 29684) (FRL–5597–1), the Agency presented its general determination that final SNURs are not expected to have a significant economic impact on a substantial number of small entities, which was provided to the Chief Counsel for Advocacy of the Small Business Administration.

D. Unfunded Mandates Reform Act (UMRA)

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government will be impacted by this proposed rule. As such, EPA has determined that this proposed rule does not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of UMRA sections 202, 203, 204, or 205 (2 U.S.C. 1531–1538 *et seq.*).

E. Executive Order 13132: Federalism

This action would not have a substantial direct effect on 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, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999).

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This proposed rule would not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This proposed rule would not significantly nor uniquely affect the communities of Indian Tribal governments, nor does it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175

(65 FR 67249, November 9, 2000), do not apply to this proposed rule.

G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This proposed rule is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use and because this action is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

In addition, since this action does not involve any technical standards, NTTAA section 12(d), 15 U.S.C. 272 note, does not apply to this action.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898 (59 FR 7629, February 16, 1994).

List of Subjects in 40 CFR Parts 721 and 725

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: February 28, 2020.

Tala Henry,

Deputy Director, Office of Pollution Prevention and Toxics.

Therefore, it is proposed that 40 CFR part 721 is amended as follows:

PART 721—[AMENDED]

■ 1. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

■ 2. Add §§ 721.11459 through 721.11461 to subpart E to read as follows:

Subpart E—Significant New Uses for Specific Chemical Substances

* * * * *

Sec.
721.11459 [Reserved]
721.11460 1-Propanaminium, N-(carboxymethyl)-N, N-dimethyl-3-[(3,5, 5-trimethyl-1-oxohexyl), amino]- inner salt.
721.11461 2-Propenoic acid, 2-methyl-, (2-oxo-1,3-dioxolan-4-yl)methyl ester.

Subpart E—Significant New Uses for Specific Chemical Substances

* * * * *

§ 721.11459 [Reserved]

§ 721.11460 1-Propanaminium, N-(carboxymethyl)-N, N-dimethyl-3-[(3,5, 5-trimethyl-1-oxohexyl), amino]-inner salt.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 1-propanaminium, N-(carboxymethyl)-N, N-dimethyl-3-[(3,5, 5-trimethyl-1-oxohexyl), amino]-inner salt. (PMN P-18-391; CAS No. 2169783-63-3) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the substance for any use that results in inhalation exposures.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11461 2-Propenoic acid, 2-methyl-, (2-oxo-1,3-dioxolan-4-yl)methyl ester.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 2-propenoic acid, 2-methyl-, (2-oxo-1,3-dioxolan-4-yl)methyl ester (PMN P-20-13; CAS No. 13818-44-5) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(j) and (o). It is a significant new use to manufacture or import greater than the confidential annual production volume identified in the PMN.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

PART 725—[AMENDED]

■ 3. The authority citation for part 725 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, 2613, and 2625(c).

■ 4. Add § 725.1080 to subpart M to read as follows:

Subpart M—Significant New Uses for Specific Microorganisms

* * * * *

§ 725.1080 Trichoderma reesei (generic).

Subpart M—Significant New Uses for Specific Microorganisms

* * * * *

§ 725.1080 Trichoderma reesei (generic).

(a) *Microorganism and significant new uses subject to reporting.* (1) The genetically-modified microorganism identified as *trichoderma reesei* strain 3CH-3 (MCAN J-19-1) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2)(i) The significant new use is any manufacturing, processing, or use of the microorganism other than in a fermentation system that meets all of the following conditions:

(A) enzyme production occurs by submerged fermentation (*i.e.,* for enzyme production, growth of the microorganism occurs beneath the surface of the liquid growth medium);

(B) any fermentation of solid plant material or insoluble substrate to which *Trichoderma reesei* fermentation broth is added after the standard industrial fermentation is completed is initiated only after the inactivation of the microorganism as delineated in 40 CFR 725.422(d).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in

§ 721.125(a) though (c) and (i) are applicable to manufacturers and processors of this microorganism.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

[FR Doc. 2020–05005 Filed 3–17–20; 8:45 am]

BILLING CODE 6560–50–P

Notices

Federal Register
Vol. 85, No. 53
Wednesday, March 18, 2020

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.

COMMISSION ON CIVIL RIGHTS

Notice of Public Meetings of the Mississippi Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Mississippi Advisory Committee (Committee) will hold a meeting on Monday June 1, 2020 at 12:00 p.m. Central time. The Committee will discuss a final draft report resulting from their study of prosecutorial discretion in the state.

DATES: The meeting will take place on Monday June 1, 2020 at 12:00 p.m. Central Time.

Public Call Information: Dial: 800–367–2403, Confirmation Code: 7030558

FOR FURTHER INFORMATION CONTACT: Melissa Wojnaroski, DFO, at *mwojnaroski@usccr.gov* or (312) 353–8311

SUPPLEMENTARY INFORMATION: Members of the public may listen to this discussion through the above call in number. An open comment period will be provided to allow members of the public to make a statement as time allows. The conference call operator will ask callers to identify themselves, the organization they are affiliated with (if any), and an email address prior to placing callers into the conference room. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and confirmation code.

Members of the public are entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be mailed to the Regional Programs Unit, U.S. Commission on Civil Rights, 230 S. Dearborn, Suite 2120, Chicago, IL 60604. They may also be faxed to the Commission at (312) 353–8324, or emailed to Corrine Sanders at *csanders@usccr.gov.* Persons who desire additional information may contact the Regional Programs Unit at (312) 353–8311.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Mississippi Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

I. Welcome and roll call
II. Discussion: Prosecutorial Discretion in Mississippi
III. Public comment
IV. Next steps
V. Adjournment

Dated: March 12, 2020.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2020–05511 Filed 3–17–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Office of the Under Secretary for Economic Affairs

RIN 0691–C111

American Workforce Policy Advisory Board; Meeting

AGENCY: Office of the Under Secretary for Economic Affairs, Department of Commerce.

ACTION: Amended notice of public meeting.

SUMMARY: The Office of the Under Secretary for Economic Affairs announces the fifth meeting of the American Workforce Policy Advisory Board (Advisory Board) will not be taking place in Mount Vernon, OH but will be conducted virtually. The short-notice change from an in-person meeting to a virtual meeting is out of an abundance of caution due to the coronavirus.

DATES: The Advisory Board will meet on March 19, 2020; the meeting will begin at 9:30 a.m. (EDT) and end at approximately 12:00 p.m. (EDT).

ADDRESSES: The meeting will be conducted virtually. The meeting is open to the public via audio conference technology. Audio instructions will be prominently posted on the Advisory Board homepage at: *https://www.commerce.gov/americanworker/american-workforce-policy-advisory-board.* Please note: The Advisory Board website will maintain the most current information on the meeting agenda, schedule, and location. These items may be updated without further notice in the **Federal Register**.

The public may also submit statements or questions via the Advisory Board email address, *AmericanWorkforcePolicyAdvisoryBoard@doc.gov* (please use the subject line ''March 2020 Advisory Board Meeting Public Comment''), or by letter to Sabrina Montes, c/o Office of Under Secretary for Economic Affairs, Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230. If you wish the Advisory Board to consider your statement or question during the meeting, we must receive your written statement or question no later than 5 p.m. (EDT) four business days prior to the meeting. We will provide all statements or questions received after the deadline to the members; however, they may not consider them during the meeting.

FOR FURTHER INFORMATION CONTACT: Sabrina Montes, c/o Office of Under Secretary for Economic Affairs, Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, (301) 278–9268, or *sabrina.montes@bea.gov.*

SUPPLEMENTARY INFORMATION: The Secretary of Commerce and the Advisor

to the President overseeing the Office of Economic Initiatives serve as the co-chairs of the Advisory Board. In addition to the co-chairs, the Advisory Board comprises 25 members that represent various sectors of the economy. The Board advises the National Council for the American Worker.

The March meeting will include updates on implementation of recommendations from the previous meetings and discussions of new recommendations under each of the four main goals of the Advisory Board:

• *Develop a Campaign to Promote Multiple Pathways to Career Success.* Companies, workers, parents, and policymakers have traditionally assumed that a university degree is the best, or only, path to a middle-class career. Employers and job seekers should be aware of multiple career pathways and skill development opportunities outside of traditional 4-year degrees.

• *Increase Data Transparency to Better Match American Workers with American Jobs.* High-quality, transparent, and timely data can significantly improve the ability of employers, students, job seekers, education providers, and policymakers to make informed choices about education and employment—especially for matching education and training programs to in-demand jobs and the skills needed to fill them.

• *Modernize Candidate Recruitment and Training Practices.* Employers often struggle to fill job vacancies, yet their hiring practices may actually reduce the pool of qualified job applicants. To acquire a talented workforce, employers must better identify the skills needed for specific jobs and communicate those needs to education providers, job seekers, and students.

• *Measure and Encourage Employer-led Training Investments.* The size, scope, and impacts of education and skills training investments are still not fully understood. There is a lack of consistent data on company balance sheets and in federal statistics. Business and policy makers need to know how much is spent on training, the types of workers receiving training, and the long-term value of the money and time spent in classroom and on-the-job training.

Sabrina L. Montes,

Designated Federal Official, American Workforce Policy Advisory Board, Bureau of Economic Analysis.

[FR Doc. 2020–05619 Filed 3–17–20; 8:45 am]

BILLING CODE 3510–MN–P

DEPARTMENT OF COMMERCE

Economic Development Administration

Notice of Petitions by Firms for Determination of Eligibility To Apply for Trade Adjustment Assistance

AGENCY: Economic Development Administration, U.S. Department of Commerce.

ACTION: Notice and opportunity for public comment.

SUMMARY: The Economic Development Administration (EDA) has received petitions for certification of eligibility to apply for Trade Adjustment Assistance from the firms listed below. Accordingly, EDA has initiated investigations to determine whether increased imports into the United States of articles like or directly competitive with those produced by each of the firms contributed importantly to the total or partial separation of the firms' workers, or threat thereof, and to a decrease in sales or production of each petitioning firm.

SUPPLEMENTARY INFORMATION:

LIST OF PETITIONS RECEIVED BY EDA FOR CERTIFICATION OF ELIGIBILITY TO APPLY FOR TRADE ADJUSTMENT ASSISTANCE

[3/4/2020 through 3/11/2020]

Firm name	Firm address	Date accepted for investigation	Product(s)
Digitronik Labs, Inc	1344 University Avenue, Suite 6100, Rochester, NY 14607.	3/6/2020	The firm manufactures and installs electrical panels and industrial control systems.
Accurate Machine Products, Inc	1520 East Delavan Drive, Janesville, WI 53546.	3/10/2020	The firm manufactures metal and plastic parts.
Kinney Tool and Die, Inc., d/b/a Ranger Die, Inc.	1300 West Randall Street, Coopersville, MI 33351.	3/11/2020	The firm manufactures stamping dies and stamped metal products.

Any party having a substantial interest in these proceedings may request a public hearing on the matter. A written request for a hearing must be submitted to the Trade Adjustment Assistance Division, Room 71030, Economic Development Administration, U.S. Department of Commerce, Washington, DC 20230, no later than ten (10) calendar days following publication of this notice. These petitions are received pursuant to section 251 of the Trade Act of 1974, as amended.

Please follow the requirements set forth in EDA's regulations at 13 CFR 315.9 for procedures to request a public hearing. The Catalog of Federal Domestic Assistance official number and title for the program under which these petitions are submitted is 11.313, Trade Adjustment Assistance for Firms.

Irette Patterson,

Program Analyst.

[FR Doc. 2020–05536 Filed 3–17–20; 8:45 am]

BILLING CODE 3510–WH–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

[Docket Number 17–BIS–0004 (consolidated)]

In the Matters of: Nordic Maritime Pte. Ltd. and Morten Innhaug Respondents; Partial Remand and Final Denial Order

This matter is before me to review the Administrative Law Judge's (ALJ) February 7, 2020 Recommended Decision and Order (RDO).[1] For the

[1] I received the certified copy of the record from the ALJ, including the original copy of the RDO, for my review on February 10, 2020. Following an extension of time authorized by the undersigned,

reasons discussed below, and upon review of the administrative record, I find there is sufficient evidence that Nordic Maritime Pte. Ltd. (Nordic) and Morten Innhaug (Innhaug and, collectively, Respondents) violated the Export Administration Regulations (EAR),[2] that Nordic did so knowingly, and that Nordic made false statements to the Bureau of Industry and Security (BIS) in the course of its investigation. I further find that the evidence supports the conclusion that Innhaug caused, aided, or abetted Nordic's unlawful reexport of the survey equipment in violation of EAR. The ALJ recommended a civil monetary penalty of $31,425,760, as well as a denial of export privileges until such time Respondents pay the civil monetary penalty. With respect to the RDO's monetary penalty recommendation, I conclude the analysis of damages in the RDO is incomplete.

For the following reasons, I affirm the findings of liability, modify the denial order to a period of 15 years, and vacate the civil monetary penalty, and remand this case to the ALJ for a reexamination of the civil monetary penalty.

I. Background [3]

BIS issued a charging letter to Respondent Nordic on April 28, 2017, alleging three violations of the EAR: (i) Nordic illegally reexported certain seismic survey equipment to Iran that were controlled by the EAR for national security and anti-terrorism reasons; (ii) Nordic acted knowingly in doing so; and (iii) Nordic made false and misleading statements to BIS during its investigation. BIS also issued a charging letter to Innhaug, alleging he aided and abetted Nordic in violating the EAR.

The Charging Letter issued against Nordic (Nordic Charging Letter) included the following specific allegations:

Charge 1 15 CFR 764.2(e)—Acting With Knowledge of a Violation

1. Between on or about May 1, 2012, and on or about April 4, 2013, Nordic Maritime transported and used items exported from the United States and subject to the Regulations with knowledge that a violation of the Regulations had occurred or was about or intended to occur in connection with the items.

2. Nordic Maritime transported to and used in Iranian waters U.S.-origin maritime surveying equipment, including specifically compass birds and streamer sections, classified under Export Control Classification Number (''ECCN'') 6A001 and controlled for National Security and Anti-Terrorism reasons (hereinafter, ''the items''). The items also were subject to the Iranian Transactions and Sanctions Regulations (''ITSR''), 31 CFR part 560, administered by the Department of the Treasury's Office of Foreign Assets Control (''OFAC''). Nordic Maritime used the items to conduct a seismic survey of Iran's off-shore Forouz B natural gas field.

3. The United States has had a long-standing and widely known embargo against Iran.

4. At all times pertinent hereto, Sections 742.4, 742.8, and 746.7 of the Regulations imposed a BIS license requirement for the export or reexport of the items to Iran. In addition, Section 746.7 of the Regulations also prohibited the export or reexport of any item subject to the Regulations if the transaction was prohibited by the ITSR. At all times pertinent hereto, the ITSR prohibited, *inter alia,* the unauthorized reexportation or supply, either directly or indirectly, of the items to Iran. *See* 31 CFR 560.204–205.

5. In order to avoid duplication regarding transactions involving items subject to both the Regulations and the ITSR, Section 746.7 of the Regulations provided that authorization did not need to be obtained from both BIS and OFAC, but instead that authorization by OFAC under the ITSR was considered authorization for purposes of the Regulations as well.

6. However, Nordic Maritime did not seek or obtain authorization from BIS, or from OFAC, in connection with the items.

7. Nordic Maritime knew at all times pertinent hereto, including as subsequently admitted in a written submission to BIS dated April 15, 2014, that the items were of U.S.-origin and that it was aware of the U.S. embargo against Iran and related U.S. export controls, including through its own licensing history of BIS license requirements concerning similar items classified under ECCN 6A001 of the Regulations.

8. In addition, on or about April 11, 2012, Nordic Maritime was warned, via a letter to its Chairman, Morten Innhaug, that its use of the items in Iranian waters would violate U.S. law and would be ''in direct breach of the terms of Re-Export License issued by the US Department of Commerce (Bureau of Industry and Security) in relation to use of the Equipment.'' (Parenthetical in original). Nordic Maritime received this warning letter from counsel to the company that at the time held a BIS reexport license for the items (hereinafter, ''[Reflect Geophysical]'') that had issued in July 2011.

9. Moreover, Nordic Maritime obtained a copy of the reexport license held by [Reflect Geophysical] no later than on or about June 29, 2012. The license by its terms did not authorize use of the items in Iranian waters or other reexport of the items to Iran by any person or entity, and specifically provided that ''no transfer, resale, or re-export of the controlled equipment is authorized without prior [U.S. Government] approval.''

10. Notwithstanding the foregoing, Nordic Maritime transported the items to and used them in Iran's Forouz B natural gas field between on or about May 1, 2012, and on or about at least April 4, 2013, without the required U.S. Government authorization.

11. As it subsequently admitted in its April 15, 2014 written submission to BIS, Nordic Maritime used the items on a vessel that it had leased from a ''Russian State owned company Seismic Geophysical Company'' and ''that had certain U.S.-origin seismic surveying equipment onboard (streamer sections and compass birds subject to the EAR and classified under ECCN 6A001) that were owned by'' [Reflect Geophysical]. (Parenthetical in original). Moreover, Nordic Maritime admittedly conducted the ''seismic survey in Iranian waters . . . under a contract that Nordic entered into with Mapna International FZE, a company based in Dubai, UAE.'' Furthermore, although feigning ignorance when it contracted to perform the seismic survey in Iranian waters that the survey on behalf of or for the benefit of Iran, Nordic Maritime admitted in its April 15, 2014 submission to BIS that ''Mapna International has significant ties to Iran'' and that ''the work for which Mapna International was contracting was in furtherance of Mapna Group's contract with the National Iranian Offshore Oil Company to [ ] explore the Forouz B natural gas field.''

12. In so transporting and using the items with knowledge that a violation of the Regulations had occurred or was about or intended to occur in connection with them, Nordic Maritime violated Section 764.2(e) of the Regulations.

Charge 2 15 CFR 764.2(a)—Reexport of Maritime Surveying Equipment to Iran Without Required License

13. BIS re-alleges and incorporates herein the allegations set forth in Paragraphs 1–12, *supra.*

14. Between on or about May 1, 2012, and on or about April 4, 2013, Nordic Maritime engaged in conduct prohibited by the Regulations when it reexported to Iran items subject to the Regulations without the required license.

15. Pursuant to Sections 742.4, 742.8, and 746.7 of the Regulations, the items—U.S.-origin maritime surveying equipment, including specifically compass birds and streamer sections, classified under Export

both the Respondents and BIS each filed timely responses to the RDO and replies to those responses. I have considered the parties' submissions in this decision.

[2] The EAR originally issued under the Export Administration Act of 1979, as amended, 50 U.S.C. 4601–4623 (Supp. III 2015) (the EAA), which lapsed on August 21, 2001. The President continued the Regulations under the International Emergency Economic Powers Act, 50 U.S.C. 1701–1708, including during the time period of the violations at issue here. On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which includes the Export Control Reform Act of 2018, 50 U.S.C. 4801–4852 (ECRA). While Section 1766 of ECRA repeals the provisions of the EAA (except for three sections which are inapplicable here), Section 1768 of ECRA provides, in pertinent part, that all rules and regulations that were made or issued under the EAA, including as continued in effect pursuant to IEEPA, and were in effect as of ECRA's date of enactment, shall continue in effect according to their terms until modified, superseded, set aside, or revoked through action undertaken pursuant to the authority provided under ECRA.

[3] For a more fulsome description of the facts and procedural background of this case, the RDO is attached as an addendum to this Partial Remand and Final Denial Order.

Control Classification Number (''ECCN'') 6A001 and controlled for National Security and Anti-Terrorism reasons—could not lawfully be exported or reexported to Iran without a BIS license. Section 746.7 of the Regulations also prohibited the export or reexport of any item subject to the Regulations if the transaction was prohibited by the ITSR. At all times pertinent hereto, the ITSR prohibited, *inter alia,* the unauthorized reexportation or supply, either directly or indirectly, of the items to Iran. *See* 31 CFR 560.204–205.

16. In order to avoid duplication regarding transactions involving items subject to both the Regulations and the ITSR, Section 746.7 of the Regulations provided that authorization did not need to be obtained from both BIS and OFAC, but instead that authorization by OFAC under the ITSR was considered authorization for purposes of the Regulations.

17. However, Nordic Maritime reexported the items to the Forouz B natural gas field in Iran without seeking or obtaining authorization from BIS, or from OFAC, in connection with the items. Nordic Maritime used the items to conduct a seismic survey of the Forouz B gas field in furtherance of Mapna Group's contract with the National Iranian Offshore Oil Company, an Iranian Government entity.

18. In so doing, Nordic Maritime violated Section 764.2(a) of the Regulations.

Charge 3 15 CFR 764.2(g)—False or Misleading Statements to BIS in the Course of an Investigation

19. BIS re-alleges and incorporates herein the allegations set forth in Paragraphs 1–18, *supra.*

20. On or about April 15, 2014, Nordic Maritime made false or misleading statements to BIS in the course of the investigation of the violations and the related unauthorized reexport to Iran described in Paragraphs 1–18, *supra.*

21. Specifically, Nordic Maritime made a written submission to BIS admitting that the company had acquired the items from [Reflect Geophysical] and that Nordic Maritime was aware that the items were of U.S. origin.

22. However, Nordic Maritime further stated that [Reflect Geophysical] had never ''(1) advised Nordic that any of the equipment onboard the vessel was re-exported pursuant to a BIS export license,'' ''(2) communicated to Nordic any BIS export license conditions'' or ''(3) provided a copy of the BIS license to Nordic.'' These statements were false or misleading.

23. In fact, Nordic Maritime knew that the items had been subject to a BIS reexport license issued in July 2011 to and was held by [Reflect Geophysical]. Nordic Maritime had been warned by counsel to [Reflect Geophysical], on or about April 11, 2012, via a letter to Nordic Maritime's Chairman, Morten Innhaug, that the items had been reexported pursuant to a BIS license. Moreover, on or about June 29, 2012, Nordic Maritime had obtained a copy of the license, including the license conditions, from [Reflect Geophysical].

24. In so making false or misleading statements to BIS during the course of an investigation, Nordic Maritime violated Section 764.2(g) of the Regulations.

Nordic Charging Letter (footnotes omitted).

BIS's charging letter against Innhaug (Innhaug Charging Letter) alleged:

Charge 1 15 CFR 764.2(b)—Causing, Aiding, and Abetting Unlicensed Reexports of Maritime Surveying Equipment to Iran

1. Between on or about May 1, 2012, and on or about April 4, 2013, Innhaug engaged in conduct prohibited by the Regulations by causing, aiding, abetting, counseling, commanding, inducing and/or permitting the unlawful reexport of U.S.-origin maritime surveying equipment to Iran by Nordic Maritime Pte Ltd., of Singapore (''Nordic Maritime'').

2. At all pertinent times hereto, Innhaug was the Chairman and majority shareholder of Nordic Maritime, and directed and/or controlled its activities.

3. Between on or about May 1, 2012, and on or about April 4, 2013, Nordic Maritime engaged in conduct prohibited by the Regulations when it reexported to Iran items subject to the Regulations without the required U.S. Government authorization, in violation of Section 764.2(a) of the Regulations.

4. Pursuant to Sections 742.4, 742.8, and 746.7 of the Regulations, the items—U.S.-origin maritime surveying equipment, including specifically compass birds and streamer sections, classified under Export Control Classification Number (''ECCN'') 6A001 and controlled for National Security and Anti-Terrorism reasons—could not lawfully be exported or reexported to Iran without a BIS license. Section 746.7 of the Regulations also prohibited the export or reexport of any item subject to the Regulations if the transaction was prohibited by the ITSR. At all times pertinent hereto, the ITSR prohibited, *inter alia,* the unauthorized reexportation or supply, either directly or indirectly, of the items to Iran. *See* 31 CFR 560.203–.205.

5. In order to avoid duplication regarding transactions involving items subject to both the Regulations and the ITSR, Section 746.7 of the Regulations provided that authorization did not need to be obtained from both BIS and OFAC, but instead that authorization by OFAC under the ITSR was considered authorization for purposes of the Regulations.

6. However, Nordic Maritime reexported the items to the Forouz B natural gas field in Iran without seeking or obtaining authorization from BIS, or from OFAC, in connection with the items. Nordic Maritime used the items to conduct a seismic survey of the Forouz B gas field and did so effectively on behalf of or for the benefit of the Iranian Government.

7. As subsequently admitted by Nordic Maritime in a written submission to BIS dated April 15, 2014, Nordic Maritime operated a vessel (the M/V Orient Explorer) that it had leased from a ''Russian State owned company Seismic Geophysical Company'' and had ''certain U.S.-origin seismic surveying equipment onboard (streamer sections and compass birds subject to the EAR and classified under ECCN 6A001) that were owned by'' [Reflect Geophysical]. (Parenthetical in original). Moreover, Nordic Maritime conducted the ''seismic survey in Iranian waters . . . under a contract that Nordic entered into with Mapna International FZE, a company based in Dubai, UAE.'' Furthermore, although feigning ignorance at the time the contract was entered, Nordic Maritime admitted in its April 15, 2014 submission that ''Mapna International has significant ties to Iran'' and that ''the work for which Mapna International was contracting was in furtherance of Mapna Group's contract with the National Iranian Offshore Oil Company to [ ] explore the Forouz B natural gas field.''

8. On or about April 11, 2012, prior to Nordic Maritime's reexport of the items to Iran, Innhaug received a cease and desist letter sent to his attention from counsel to the company (hereinafter, ''[Reflect Geophysical]'') that at the time held a BIS reexport license for the items. That letter indicated [Reflect Geophysical's] understanding, which was accurate, that the M/V Orient Explorer was en route with the items on board and would be deployed in Iranian waters after making a port of call in Dubai, United Arab Emirates. The letter warned that Nordic Maritime's use of the items in Iranian waters would violate U.S. law and would be ''in direct breach of the terms of Re-Export License issued by the US Department of Commerce (Bureau of Industry and Security) in relation to use of the Equipment.'' (Parenthetical in original).

9. As alleged above, Nordic Maritime reexported the items to and used them in Iran's Forouz B natural gas field beginning on or about May 1, 2012, in violation of the Regulations. In no later than June 2012, while conducting the seismic survey, Nordic Maritime obtained a copy of the license from [Reflect Geophysical]. The license by its terms did not authorize use of the items in Iranian waters or other reexport of the items to Iran by any person or entity, and specifically provided that ''no transfer, resale, or re-export of the controlled equipment is authorized without prior [U.S. Government] approval.'' Nonetheless, Nordic Maritime continued to conduct the survey in violation of the Regulations until at least on or about April 4, 2013.

10. As Nordic Maritime's chairman and majority owner, Innhaug directed and/or controlled Nordic Maritime. In addition, he also had received actual notice providing him with personal knowledge that Nordic Maritime was about to engage, and then was engaging on an ongoing or continuing basis, in conduct in violation of the Regulations. Through his actions and/or failure to act, Innhaug caused, aided, abetted, counseled, commanded, induced and/or permitted Nordic Maritime's unlawful reexport of the items to Iran and their use in Iranian waters without the required U.S. Government authorization.

11. In so doing, Innhaug violated Section 764.2(b) of the Regulations.

Innhaug Charging Letter (footnotes omitted).

Nordic and Innhaug answered the charging letters on June 1, 2017, and

requested a 30-day stay of the proceedings. The stay was denied, and the proceedings continued for approximately two years,[4] but there are a few events worth highlighting.

The parties disputed whether the Respondents had the ability to pay any fine should the Respondents be found liable. After some filings back and forth—and after being provided several opportunities to comply by the ALJ by way of orders on May 22 and 24, 2019—the Respondents advised the ALJ that they would not participate in the upcoming trial. Respondents' counsel filed a notice on June 10, 2019 that counsel was not authorized by Respondents to appear at the hearing the next day to discuss Respondents' arguments regarding inability to pay any fine. At the June 11, 2019 hearing, the ALJ ruled that the Respondents would be precluded from raising any arguments regarding an inability to pay.

Following a hearing on June 11, 2019, and post-hearing briefing by the parties,[5] the ALJ issued the RDO. The ALJ found Respondents liable on all counts. The ALJ also recommended that Respondents be fined €23.6 million—converted to $31,425,760 [6]—or twice the amount of Respondent Nordic's contract with Mapna. The ALJ recommended the civil monetary penalty be jointly and severally imposed on Respondents.

II. Review Under Section 766.22

A. Jurisdiction

The undersigned has jurisdiction under Section 766.22 of the EAR.[7] While this case was pending before the ALJ, the Export Control Reform Act of 2018 (ECRA) became law. *See* Public Law 115–232 (2018) (codified at 50 U.S.C. 4801–4852). At the time of the offenses, however, the previous statutory scheme, the Export Administration Act of 1979, had lapsed and, as noted above, the EAR was kept in effect under the International Emergency Economic Powers Act (IEEPA).

ECRA provided that the authority of the EAR and any judicial or administrative proceedings pending on the date of enactment would be unaffected. *See* 50 U.S.C. 4826.

B. Liability

The RDO correctly sets out the standard for proving violations of the EAR. In particular, BIS must prove the allegations by reliable, probative, and substantial evidence. BIS's burden is one of preponderance of the evidence, which means it is more likely than not that the Respondents committed the violations charged.

The RDO contains a detailed review of the record relating to the merits in this case, and the findings of liability are affirmed.

1. Respondent Nordic Charge 2—Reexporting Equipment to Iran [8]

The evidence in this case is conclusive that Respondent Nordic reexported seismic equipment to Iran without the license required under the EAR. That reexport violated 15 CFR 764.2(a). In fact, Nordic's own answer before the ALJ concedes this point, but argues that it did not do so knowingly. Answer of Respondent Nordic Pte. and Demand for a Hearing ¶¶ 2, 6, 8–10, 17.

As the RDO correctly outlines, section 764.2(a) prohibits *all* violations of the EAR. In addition, violations of section 764.2(a) are strict liability offenses. *See In the Matter of Wayne LaFleur,* 74 FR 5916, 5918 (Feb. 3, 2009). BIS, therefore, need not prove knowledge to sustain a violation of section 764.2(a).

The parties do not dispute number of material facts. Neither party contests that the survey equipment at issue in this case was classified under Export Control Classification Number (ECCN) 6A001. The parties do not dispute that the equipment was possessed by Respondent Nordic in Iranian territorial waters, and was therefore reexported. The parties also agree that neither of the Respondents had a license to reexport the survey equipment.

These uncontested facts support the RDO's finding that Nordic violated the EAR by reexporting the survey equipment when it used the equipment in Iranian territorial waters. Even if the facts above were contested, the record amply supports that Nordic reexported the equipment without a license. I therefore affirm the RDO's finding on this count.

2. Respondent Nordic Charge 1—Acting With Knowledge of an EAR Violation

The evidence in this case strongly supports the conclusion that Nordic reexported the survey equipment with knowledge that doing so would violate the EAR. *See* 15 CFR 764(e). The EAR defines ''knowledge'' as ''not only positive knowledge that the circumstance exists or is substantially certain to occur, but also an awareness of a high probability of its existence or future occurrence.'' 15 CFR 772.1. A factfinder can infer knowledge where the party exhibits a ''conscious disregard of facts known to a person'' or willful avoidance of such facts. *Id.*

In this case, the record is clear that Nordic was put on notice no later than April 2012 that the use of the survey equipment in Iranian waters would require an export license. The company that leased the seismic survey equipment, Reflect Geophysical, sent a cease and desist letter to Nordic that any use in Iranian waters would violate the license Reflect Geophysical obtained from BIS. Were this not enough, Reflect Geophysical provided a copy of the license to Nordic in June 2012.

Although it is clear Nordic had actual notice, even if one were not convinced, the RDO lays out a history of communications between Reflect Geophysical and Nordic concerning their dispute about the scope of the use of the equipment. I agree with the RDO's finding that ''[t]hese communications . . . are telling and lead to the conclusion that the parties discussed the use of equipment in Iranian waters.''

The record amply supports the RDO's statement that ''[t]he evidence is conclusive'' that Nordic had knowledge that using the survey equipment in Iranian waters would violate the EAR. I affirm the RDO's conclusion on this count.

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[4] Part of the delay was the result of the Supreme Court's decision in *Lucia* v. *SEC,* 138 S Ct. 2044 (2018), in which the Court concluded many administrative law judges are ''[o]fficers of the United States'' for purposes of the Constitution's Appointments Clause. *See id.* at 2055. As a result, a new ALJ was assigned and for the most part was required to start over and redo the proceedings conducted before the Court's decision in *Lucia.* The events described *infra* occurred after the ALJ was appointed in compliance with the Court's ruling in *Lucia.*

In addition to the *Lucia*-related delays, the federal government experienced a lapse of appropriations from December 22, 2018 to January 25, 2019.

[5] In their post-hearing briefing before the ALJ, the Respondents sought to resurrect their already-barred argument regarding an inability to pay by way of two attachments. The ALJ struck those attachments and did not consider them. In their brief before the undersigned, Respondents again attach materials related to their purported inability to pay. For the reasons discussed in this Partial Remand and Final Denial Order, the Respondents have waived their ability to argue an inability to pay, and I did not consider the attachments to their brief.

[6] The ALJ used the conversion rate applicable when Nordic entered the contract with Mapna. Because the contract was dated ''March 2012,'' the ALJ used March 1, 2012 for the conversion date. I agree March 1, 2012 is the appropriate conversion date.

[7] Because the conduct at issue in this case took place in 2012 and 2013, those versions of the EAR govern the substantive aspects of the case.

The procedural aspects of this case are governed by the 2019 version of the EAR.

[8] The RDO considers Charge 2 first. For the sake of consistency, I will do so as well.

3. Respondent Nordic Charge 3—Making False and Misleading Statements

BIS also charged Nordic with making false statements during a purported voluntary disclosure reporting the conduct at issue in this case.[9] The evidence supports the RDO's finding that Nordic made false and misleading statements to BIS during its investigation, in violation of 15 CFR 764.2(g).

I agree with the RDO's finding that BIS opened its investigation after it received Reflect Geophysical's April 17, 2012 letter to Nordic regarding the latter's possible use of the survey equipment in Iranian waters. The basis for Charge 3 was Nordic's April 15, 2014 letter to BIS. That letter mentioned an interview the company had with a BIS special agent regarding the conduct in this case.

In the April 15, 2014 letter, Nordic claimed Reflect Geophysical failed to advise Nordic that the survey equipment was subject to a BIS license, that there were license conditions regarding the survey equipment, and that Reflect Geophysical never provided a copy of the license to Nordic. As the RDO concluded, ''[n]one of these statements were true.'' The April 2012 letter made reference to the BIS license and the conditions related thereto. Reflect Geophysical also provided a copy of the license with the June 2012 lease agreement between the companies.

The evidence supports the charge that Nordic's statements in the April 15, 2014 were false and misleading with respect to BIS's investigation. I therefore affirm the RDO's finding that Nordic made false and misleading statements to BIS.

4. Respondent Innhaug Charge 1—Causing, Aiding, and Abetting Any Act Prohibited by the EAR

The evidence also supports the conclusion that Innhaug caused, aided, or abetted Nordic's unlawful reexport of the survey equipment in violation of 15 CFR 764.2(b).

Innhaug was, at all relevant times, the Chairman and majority shareholder of Nordic. Under the EAR, a corporate officer can be held liable for acts of the corporation. *See In the Matter of Trilogy Int'l,* 83 FR 9259, 9261 (Mar. 5, 2018) (citing a remand order from the Acting Under Secretary to treat a corporation and its executive separately because ''it is well established that a corporate officer can be charged with causing, aiding or abetting the corporation's underlying violations'') (internal quotation marks omitted).

The April 11, 2012 cease and desist letter from Reflect Geophysical was addressed to Innhaug. As a result, he was aware of the concerns regarding the potential use of the survey equipment in Iranian waters. Innhaug was also a signatory to the time-charter agreement for the vessel used to carry the survey equipment into Iranian waters. That was, the RDO noted, ''an integral part of the ultimate violation.'' Finally, Innhaug admitted to reviewing the April 15, 2014 letter to BIS, which formed the basis for the false and misleading statements charge against Nordic.

The evidence supports the conclusion that Innhaug aided and abetted Nordic's violations of the EAR, and I affirm the RDO's conclusion.

C. Penalties

The EAR permits the undersigned to impose: (1) A civil monetary penalty; (2) a denial of export privileges, and (3) an exclusion from practicing as a representative in a licensing transaction. *See* 15 CFR 764.3(a)(1)–(3). In addition, the relevant statutory provision in effect at the time of the offense permits imposition of a civil penalty or $289,238 per violation[10] or ''an amount that is twice the amount of the transaction that is the basis of the violation with respect to the penalty imposed.'' 50 U.S.C. 1705(b)(2).

1. Civil Monetary Penalty

The RDO recommended a civil monetary penalty jointly and severally on both Respondents. The ALJ took the value of the contract between Nordic and Mapna—€11.3 million—doubled it, as permitted under IEEPA, and converted it to U.S. dollars. The resulting penalty is $31,425,760. The ALJ did not suspend any portion of the fine.

The ALJ applied the factors used by BIS in settlement cases, found in 15 CFR part 766, Supp. No. 1.[11] Although instructive, this case was not settled; rather, the case proceeded to a full hearing before an ALJ—a hearing that Respondents decided the day before to decline to participate. In any event, I agree with the ALJ's application of the factors, both mitigating and aggravating. I also agree with the RDO and BIS that IEEPA permits a civil monetary penalty that is ''twice the amount of the transaction that is the basis of the violation with respect to which the penalty is imposed.'' 50 U.S.C. 1705(b)(2). In this case, the relevant transaction—that is, the transaction that caused the illegal reexport of the survey equipment to Iran—was the contract between Nordic and Mapna.

Respondents' conduct in this case was unquestionably serious, and it warrants a significant sanction.[12] The RDO analyzes the factors for settlement cases, but it does not provide any analysis regarding how this penalty fits into other cases. I agree with BIS's position before the ALJ that penalties in litigated cases should be higher than settlement cases based on similar conduct. Indeed, the EAR guidelines on settlement gave the respondents notice that ''penalties for settlements reached after the initiation of litigation will usually be higher than those'' that settle. 15 CFR part 766, Supp. No. 1.

The record does not, at this point, support the civil monetary penalty amount recommended in this case. Even accounting for the fact that this case was litigated, the penalty here is disproportionate to similar cases charged by BIS notwithstanding that many of these cases are subject to a lower statutory penalty amount. Further, even taking into account, for example, cases proceeding through litigation (even if defaulted), relating to exports to Iran, and with a sustained charge of a knowing violation of the EAR, the penalty in this case is out of proportion.[13] There are a number other cases in this vein where the Under Secretary imposed *no* civil penalty at all. *See, e.g., In the Matter of Ali Asghar Manzarpour,* 73 FR 12,073 (Mar. 6, 2008) (three violations, including

[9] The parties dispute whether Nordic's disclosure was truly voluntary, given that it was submitted after BIS had begun its investigation. The evidence in this case demonstrates that Respondents' purported voluntary disclosure came after BIS had begun its investigation and was therefore not a voluntary disclosure under the EAR. *See* 15 CFR 764.5(b)(3). I would note, however, that even if this were a voluntary disclosure. ''a respondent who makes false statements to BIS during an investigation cannot properly claim, and should not be accorded, mitigation credit relating to the subject of those false statements.'' *In the Matter of Manoj Bhayana,* 76 FR 18,716, 18,718 (Apr. 5, 2011). Put more bluntly: ''a respondent should not be allowed to reap any benefit from such false or misleading statements.'' *Id.*

[10] The maximum civil penalty amount is subject to increase pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, Public Law 114–74, 701 (2015). *See* 15 CFR 6.4(b)(4).

[11] The ALJ appropriately used the 2014 version of the CFR to analyze the settlement factors.

[12] By using the term ''serious,'' I am not implying that Respondents' conduct falls short of egregiousness, as noted in the EAR. *See* 15 CFR part 766, Supp. No. 1, § IV.B. I instead leave that to the ALJ to consider on remand.

[13] This method of considering penalties was used in *In the Matter of Petrom GmbH International Trade,* and I agree with its utility. *See* 70 FR at 32,744 (''[T]he proposed denial order is consistent with penalties imposed in recent cases under the Regulations involving shipments to Iran.'') (collecting cases).

knowledge, and no civil penalty); *In the Matter of Teepad Electronic General Trading,* 71 FR 34,596 (June 15, 2006) (five violations, including knowledge, and no civil penalty); *In the Matter of Swiss Telecom,* 71 FR 32,920 (June 7, 2006) (nine violations, including knowledge, and no civil penalty); *In the Matter of Arian Transportvermittlungs GmbH,* 69 FR 28,120 (May 18, 2004) (two violations, including knowledge, and no civil penalty); *In the Matter of Adbulamir Mahdi,* 68 FR 57,406 (Oct. 3, 2003) (six violations, including knowledge, and no civil penalty); and *In the Matter of Jabal Damavand General Grading Company,* 67 FR 32,009 (May 13, 2002) (four violations, including knowledge, and no civil penalty).

In their briefing before the undersigned, both parties cite *In the Matter of Aiman Ammar,* 80 FR 57,572 (Sept. 24, 2015), as being in their favor. In that case, respondents settled a case with eight violations of the EAR related to reexport of computer equipment to Syria, including a charge related to a knowing violation. *Id.* at 57,574. The total value of the transactions at issue in that case was approximately $3.6 million. *Id.* at 57,573–57,575. The settlement agreement assessed a $7,000,000 civil monetary penalty, with all but $250,000 suspended for two years and conditioned on no further export control violations. *Id.* at 57,575. Similarly, at the hearing before the ALJ, BIS posited that *In the Matter of Yavuz Cizmeci,* 80 FR 18,194 (Apr. 3, 2015), advanced BIS's penalty arguments. That case, however, simply confirms the analysis above: The ALJ on remand should conduct a proportionality analysis in this case. In *Cizmeci,* BIS charged the respondent with a single count of aiding and abetting violations of a temporary denial order related to the acquisition of a Boeing 747 aircraft by Iran Air. *Id.* at 18,194. The total value of that transaction was $5.3 million. *Id.* In the course of settling that case, BIS accepted a $50,000 civil penalty, less than 1% of the value of the transaction. *Id.* at 18,195.

Even cases related to false statements to BIS in the course of an investigation, there appears to be little precedent for a civil monetary penalty like the one given here. *See, e.g., In the Matter of Manoj Bhayana,* 76 FR 18,716 (Apr. 5, 2011) (on Under Secretary review of a false statement to BIS during an investigation, no civil monetary penalty and a two-year denial order); *In the Matter of William Kovacs,* 72 FR 8967 (Feb. 28, 2007) (on Under Secretary review of a false statement to BIS during an investigation, a $66,000 civil monetary penalty and a five-year denial order); *see also In the Matter of Saeid Yahya Charkhian,* 82 FR 61,540 (Dec. 28, 2017) (settlement agreement containing a charge of making a ''false or misleading statement to BIS and other U.S. Government officials'' with no civil monetary penalty); *In the Matter of Berty Tyloo,* 82 FR 4842 (Jan. 17, 2017) (settlement agreement containing a charge of making a false statement to BIS with no civil monetary penalty).

A wider view of BIS's cases tells a similar story. In *In the Matter of Eric Baird,* 83 FR 65,340 (Dec. 20, 2018), BIS entered into a settlement agreement for 166 violations of the EAR, but with no knowledge charges. The parties settled for $17,000,000, with $7,000,000 suspended on the condition of prompt payment. *Id.* at 65,342. That case had a related criminal resolution, in which Baird pled guilty to felony smuggling.[14] BIS settled a related case, consisting of 150 violations of the EAR, for $27,000,000, with $17,000,000 suspended. *In the Matter of Access USA Shipping, LLC. See* Order dated Feb. 9, 2017, available at *www.bis.doc.gov*. Similarly, the respondent in *In the Matter of Petrom GmbH International Trade,* 70 FR 32,743 (June 6, 2005), committed thirteen violations of the EAR, including a knowing violation of the EAR. The Under Secretary affirmed a civil penalty in the amount of $143,000—the maximum amount permitted under the statute at the time—on transactions valued at approximately $100,000. *Id.* at 32,744, 32,750–51.

Baird and *Access USA* are not the outer limits of the penalties available in any case. But, compared to the number of violations here, and that none of the penalty in this case was suspended, there are questions about whether the penalty recommended in this case is proportional to Respondents' conduct in this case. During the hearing and in several portions of its brief before the ALJ, BIS argued these facts are ''egregious,'' with the post-hearing briefing saying the facts here constitute ''one of the most egregious set of facts ever encountered by BIS.'' If that is so, BIS should be able to make the record before the ALJ to conduct a comparative analysis.

Apart from the amount of the fine in this case, several of the cases above demonstrate that BIS occasionally suspends portions of a civil monetary penalty, particularly in cases with penalties over $1,000,000. *See Baird* (assessing a penalty of $17,000,000 with $10,000,000 suspended); *Access USA* (assessing a penalty of $27,000,000 with $17,000,000 suspended); *Ammar* (assessing a penalty of $7,000,000 with $6,750,000 suspended). The ALJ in this case did not suspend any of the civil penalty. Respondents argue in their briefing that BIS suspends at least a portion of the civil monetary penalty in 43% of cases since 2009. Without attesting to the veracity of that figure, it remains short of a majority. In any event, the significant penalties with a portion suspended in the cases above are all settlements; that is, the parties agreed to it. In this case, Respondents participated in the hearing, up to a point. They required BIS to prepare for and present at a hearing before the ALJ. Because I am vacating and remanding the civil monetary penalty, I need not decide at this point whether the suspension of any portion is appropriate. It may well not be, as the ALJ concluded in the RDO, but I will leave that issue open for the ALJ to consider on remand.

Given the range of outcomes in previous resolutions, it is preferable for the ALJ to conduct the proportionality analysis in the first instance. Although IEEPA—and now ECRA—permits a reviewing authority to impose twice the amount of the transaction, the ALJ on remand should reconsider the civil monetary penalty in light of the penalties issued in previous cases, recognizing some of them were the statutory maximum at the time. Respondents' conduct was serious, and they should be punished. The ALJ was correct that any penalty ''should be such that it dissuades future violations of this sort, and acts as a strong deterrent against this type of behavior.'' Viewed through this lens, it may well be that the civil monetary penalty in case will be substantial. Perhaps it will remain unchanged. But the record would benefit from further development on the issue of proportionality.

As a result, I vacate the ALJ's imposition of a civil monetary penalty, and this case is remanded to the ALJ for a reexamination of the penalty in view of the guidance provided above.

2. Denial Order

In addition to the civil penalty, the ALJ recommended the imposition of a temporary denial order on Respondents to run until such time as Respondents pay the civil monetary penalty in full. Although Respondents have waived their inability-to-pay argument, I conclude that a denial order unbounded in time does not serve the ends of

[14] U.S. Dep't of Justice, ''Former Florida CEO Pleads Guilty To Export Violations And Agrees To Pay Record $17 Million To Department Of Commerce,'' Dec. 14, 2018, *https://www.justice.gov/usao-mdfl/pr/former-florida-ceo-pleads-guilty-export-violations-and-agrees-pay-record-17-million.*

justice. Accordingly, I conclude a denial order of 15 years will adequately vindicate BIS's interests in this case.[15]

A review of the same cases cited above—those related to Iran and a knowing violation of the EAR—is useful. In each of those, the Under Secretary affirmed denial orders for a specified period of years. *See, e.g., In the Matter of Ali Asghar Manzarpour,* 73 FR 12,073 (Mar. 6, 2008) (affirming a 20-year denial order period); *In the Matter of Teepad Electronic General Trading,* 71 FR 34,596 (June 15, 2006) (affirming a 10-year denial order period); *In the Matter of Swiss Telecom,* 71 FR 32,920 (June 7, 2006) (affirming a 10-year denial order period); *In the Matter of Petrom GmbH International Trade,* 70 FR 32,743 (June 6, 2005) (affirming a 20-year denial order period); *In the Matter of Arian Transportvermittlungs GmbH,* 69 FR 28,120 (May 18, 2004) (affirming a 10-year denial order period); *In the Matter of Adbulamir Mahdi,* 68 FR 57,406 (Oct. 3, 2003) (affirming a 20-year denial order period); and *In the Matter of Jabal Damavand General Grading Company,* 67 FR 32,009 (May 13, 2002) (affirming a 10-year denial order period).

I conclude BIS's position requesting a 15-year denial period is appropriate, and I modify the denial order period to run 15 years from the date of this Partial Remand and Final Denial Order.

D. Miscellaneous Items

Several other items require brief consideration. First, Respondents requested a meeting with the undersigned to discuss the case. The EAR provides that the Under Secretary's ''review will ordinarily be limited to the written record for decision, including the transcript of any hearing, and any submissions by the parties concerning'' the RDO. 15 CFR 766.22(c). I agree with BIS's argument that to do so would be a departure from the normal practice. In any case, it is unnecessary here. The record and RDO are clear and support the findings of liability. In addition, because I am vacating the monetary penalties, the ALJ will have the opportunity to hold arguments, should he so choose, to consider the remaining issue in this case; although I would note that Respondents declined to participate in the June 11, 2019 hearing, and there are reasons not to reward them for their choice.

Respondents also point to the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA)[16] for the proposition that ''under the appropriate circumstances,'' I am permitted to grant a ''waiver of civil penalties for statutory or regulatory violations by small entities.'' Although true, there are several problems with Respondents' request. The charging letters for both sets of Respondents point to the U.S. Small Business Administration's Ombudsman to discuss the potential applicability of the SBREFA. There is no evidence in the record that Respondents did so, and they do not claim to have done so in their brief. In any event, Respondents declined to participate in the hearing—including to appear and present arguments about whether Nordic is a small business, the financial implications or any penalties, or similar issues. There is little reason to entertain an eleventh-hour argument on this point.

* * * * *

Accordingly, based on my review of the RDO and entire record, I affirm the findings of liability in the RDO, I vacate and remand for reconsideration the civil monetary penalty, and modify the recommended period of the denial order to a period of 15 years.

Accordingly, it is therefore ordered:

First, the findings of liability are affirmed against the Respondents.

Second, the civil monetary penalty is vacated and remanded for additional consideration as discussed above.

Third, for a period of 15 years from the date of this Order, Nordic Marine Pte, Ltd., with the last known address of 3 HarbourFront Place, #04–03 HarbourFront Tower 2, Singapore 099254, and Morten Innhaug, with a last known address of 16 Keppel Bay Drive #04–20 Caribbean at Keppel Bay, Singapore 098643 and when acting for or on their behalf, their successors, assigns, employees, agents, or representatives (each a ''Denied Person'' and collectively the ''Denied Persons'') may not, directly or indirectly, participate in any way in any transaction involving any commodity, software or technology (hereinafter collectively referred to as ''item'') exported or to be exported from the United States that is subject to the EAR, or in any other activity subject to the EAR, including, but not limited to:

A. Applying for, obtaining, or using any license, license exception, or export control document;

B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item exported or to be exported from the United States that is subject to the EAR, or engaging in any other activity subject to the EAR; or

C. Benefitting in any way from any transaction involving any item exported or to be exported from the United States that is subject to the EAR, or from any other activity subject to the EAR.

Fourth, that no person may, directly or indirectly, do any of the following:

A. Export or reexport to or on behalf of a Denied Person any item subject to the Regulations;

B. Take any action that facilitates the acquisition or attempted acquisition by a Denied Person of the ownership, possession, or control of any item subject to the EAR that has been or will be exported from the United States, including financing or other support activities related to a transaction whereby a Denied Person acquires or attempts to acquire such ownership, possession or control;

C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from a Denied Person of any item subject to the EAR that has been exported from the United States;

D. Obtain from a Denied Person in the United States any item subject to the EAR with knowledge or reason to know that the item will be, or is intended to be, exported from the United States; or

E. Engage in any transaction to service any item subject to the EAR that has been or will be exported from the United States and which is owned, possessed or controlled by a Denied Person, or service any item, of whatever origin, that is owned, possessed or controlled by a Denied Person if such service involves the use of any item subject to the Regulations that has been or will be exported from the United States. For purposes of this paragraph, servicing means installation, maintenance, repair, modification or testing.

Fifth, after notice and opportunity for comment as provided in section 766.23 of the EAR, any person, firm, corporation, or business organization related to a Denied Person or the Denied Persons by ownership, control, position of responsibility, affiliation, or other connection in the conduct of trade or business may also be made subject to the provisions of this Order.

Sixth, this Order shall be served on Respondents Nordic Maritime Pte Ltd. and Morten Innhaug and on BIS, and shall be published in the **Federal Register**. In addition, the ALJ's Recommended Decision and Order shall be published in the **Federal Register**.

[15] The ALJ in fact potentially exceeded even BIS's requested denial order period. BIS requested a denial order of 15 years.

[16] *See* Public Law 104–121 (1996) (codified at various sections of the U.S. Code).

The findings of liability and the denial order, which constitute final agency action in this matter, are effective immediately.

Issued this 11th day of March, 2020.

Cordell A. Hull,

Acting Under Secretary of Commerce for Industry and Security.

United States Department of Commerce, Bureau of Industry and Security, Washington, DC 20230

In the Matters of: Nordic Maritime Pte. Ltd. and Morten Innhaug, Respondent

17 BIS–0004 (consolidated)

Certificate of Service

I hereby certify that, on March 11, 2020, I caused the foregoing Partial Remand and Final Denial Order to be served upon:

Gregory Michelsen, Esq., Zachary Klein, Esq., U.S. Department of Commerce, Office of Chief Counsel for Industry and Security, 14th & Constitution Avenue NW, Washington, DC 20230, *Gmichelsen@doc.gov*, *ZKlein@doc.gov,* (Electronically).

Douglas N. Jacobson, Esq., JACOBSON BURTON KELLEY PLLC, 1725 I Street NW—Suite 300, Washington, DC 20006, *Djacobson@jacobsonburton.com*, (Electronically).

Honorable Dean C. Metry, Administrative Law Judge, U.S. Coast Guard, U.S. Courthouse, 601 25th St., Suite 508A, Galveston, TX 77550, *Janice.m.emig@uscg.mil*, (Electronically).

ALJ Docketing Center, Attention: Hearing Docket Clerk, 40 S. Gay Street, Room 4124, Baltimore, MD 21202–4022, *aljdocketcenter@uscg.mil*, (Electronically).

Office of the Under Secretary for Industry and Security

United States Department of Commerce, Bureau of Industry and Security, Washington, DC

In the Matters of: Nordic Maritime Pte. Ltd., and Morten Innhaug, Respondents.

17 BIS–0004

Recommended Decision and Order

The Bureau of Industry and Security (BIS or Agency) initiated this administrative enforcement action against Nordic Maritime Pte. Ltd. (Respondent Nordic) and Morten Innhaug (Respondent Innhaug) on April 28, 2017. BIS alleges Respondent Nordic committed three violations and Respondent Innhaug committed one violation of the Export Administration Regulations (EAR or Regulations). 15 CFR parts 730–74 (2012–14). The first three allegations allege Respondent Nordic: (1) Illegally reexported certain equipment to Iran; (2) acted with knowledge when it illegally reexported the equipment; and (3) made false and misleading statements during the BIS investigation.[17] The single charge against Respondent Innhaug alleges he aided and abetted Respondent Nordic in violating the regulations.

As set forth below, I find BIS proved the allegations in the charging letters. I recommend Respondents be fined in the amount of $31,425,760.00 dollars. I further recommend the Under Secretary impose a standard denial order as described below until Respondents repay the fine in full.

Background

After BIS filed two separate charging letters against Respondents separately, the Chief Administrative Law Judge (CALJ) of the United States Coast Guard (USCG), consolidated 17–BIS–0003 and 17–BIS–0004. *See* 5 U.S.C. 3344 and 5 CFR 930.208. Thereafter, the CALJ set deadlines for discovery and motion practice, as well as establishing a hearing date.

On February 2, 2018, the CALJ issued an order partially granting BIS' Motion for Summary Decision. *See* Docket Entry 42. The February 2, 2018 Order agreed there were no material issues of fact whether Respondents committed the allegations in the charging letters but did not, however, address the appropriate sanction to levy against Respondents for the proved violations. Noting a lack of sufficient briefing on the issue, the CALJ set a sanction hearing to commence on February 6, 2018, in Baltimore, Maryland.

After the hearing on February 6, 2018, but before the CALJ issued a sanction decision, the United States Supreme Court decided *Lucia* v. *SEC.,* on June 21, 2018. 138 S. Ct. 2044 (2018). *Lucia* declared SEC ALJs ''Officers of the United States'' and required an appointment in accordance with the Appointments Clause in Art. II, § 2, cl. 2 of the U.S. Constitution. Ultimately, the Court concluded SEC ALJs were not properly appointed, and agreed the SEC respondents were entitled to a new ''hearing'' before a new, properly appointed ALJ on remand. *Lucia,* 138 S. Ct. at 2055.

Relying on *Lucia,* Respondents filed motions attacking USCG ALJ appointments. Agreeing with Respondents in part, the CALJ issued an Order on October 19, 2018, recognizing he was similarly situated to SEC ALJs. The CALJ acknowledged he was not properly appointed under the Appointments Clause when he issued the order granting partial summary decision and when he presided over the sanction hearing in this matter. Accordingly, the CALJ reassigned this matter to the undersigned ALJ per the Supreme Court's discussion in *Lucia.* 138 S. Ct. at 2055 (discussing reassignment to a constitutionally appointed ALJ as the proper recourse).

Upon reassignment, and after reviewing Respondents' pending motions and BIS' oppositions, the undersigned ALJ held a telephone conference on November 8, 2018. During the conference, the parties agreed this matter should be reset for a hearing and that CALJ's order partially granting summary decision did not effectively dispose of the allegations in the charging letters because of his improper appointment at the time he issued the decision. However, the parties disagreed on the need for additional discovery and/or more time to file additional motions in this matter. The undersigned directed the parties to file legal memoranda addressing the need for further discovery; both parties complied on December 3, 2018.

Before the undersigned had the opportunity to decide the pending motions, the United States Department of Homeland Security, the parent department of the USCG, experienced a lapse in appropriations beginning on December 22, 2018. The funding lapse persisted until January 25, 2019, during which time the court's staff was not permitted to report for duty.

After the government shutdown, the undersigned issued an Order on February 1, 2019, granting Respondents' request to partially reopen discovery. The February 1, 2019 Order noted Respondents' well-reasoned argument that new discovery should be permitted because Respondents' ability to pay any levied sanction (if one is imposed) might have changed since the original discovery exchange in 2017. However, the undersigned did not grant unfettered discovery; the parties were only permitted to update already existing discovery responses or conduct additional discovery that did not already exist. *See* February 1, 2019 Order.

On April 12, 2019, Respondents provided BIS with updated responses to a request for production of documents, which BIS propounded in 2017. In its updated production, Respondents provided BIS with one page concerning

[17] Reexport means to ship an item subject to the EAR from one foreign country to another foreign country. *See* 15 CFR 734.14.

Respondent Innhaug's ability to pay a civil penalty and two pages of documents concerning Respondent Nordic's ability to pay a civil penalty.

BIS filed a Motion in Limine on April 26, 2019, arguing Respondents' updated production was insufficient. Respondents did not file a timely response to BIS' April 26, 2019 motion, and did not timely seek permission from the undersigned for additional time to file a response. BIS also filed a Motion for Summary Judgment on May 8, 2019.

The undersigned issued two notable orders on May 22, 2019, and May 24, 2019, in response to BIS' motions. The May 22, 2019 Order instructed Respondents to produce all documents responsive to BIS' Request for Production 5, 6, and 7, and noted that if Respondents failed to comply, the undersigned may grant BIS' request to prevent Respondents from asserting an inability to pay argument at the hearing. In the May 24, 2019 Order, the court again observed Respondents' obligation to comply with the May 22, 2019 Order, but denied BIS' request to enter summary judgment.

Thereafter, BIS renewed its Motion in Limine on June 4, 2019, asking the undersigned to prevent Respondents from asserting an inability to pay argument because Respondents failed to comply with the discovery orders issued in this case. *See* May 22, 2019 Order (permitting BIS to renew motion). Respondents filed an opposition to BIS' renewed motion, and filed a notice specifically informing the undersigned ALJ that Respondents would not appear at the June 11, 2019 hearing, and would not permit their attorney of record to appear on their behalf.

On June 11, 2019, the undersigned ALJ convened a hearing in Baltimore, Maryland. Gregory Michelsen, Esq., and Zachary Klein, Esq., appeared on behalf of the BIS. However, in keeping with the June 11, 2019 Notice, neither Respondents nor Respondents' counsel appeared at the hearing.

At the beginning of the hearing, BIS renewed their motion to bar Respondents from raising the inability to pay argument as a result of the discovery violations. The undersigned agreed and granted BIS' motion to bar Respondents from asserting the inability to pay argument. Tr. 12. Thereafter, BIS called three witnesses and offered 17 exhibits, all of which were admitted.

After the hearing, BIS filed a post-hearing brief on August 15, 2019. Respondents filed a post-hearing brief on August 16, 2019, and BIS replied on September 13, 2019. Briefing is closed in this case and this matter is ripe for decision.

Preliminary Evidentiary Issues

Before turning to the substance of this case, the undersigned finds it necessary to address the exhibits BIS attached to its post-hearing brief and attachments accompanying Respondents' post-hearing brief. I address each in turn.

a. A. BIS' Exhibits

A review of BIS' brief shows it did not cite to the 17 exhibits entered and numbered at the hearing. Instead, without permission from the ALJ, BIS' brief cites to 27 exhibits. Of the 27 exhibits, some were admitted at the hearing, others were incorporated in the record at various points during this entire litigation, and at least one was created after the hearing. BIS' mixture of these exhibits has the potential to cause great confusion. To remedy the confusion, and to prevent further delay of this matter, all exhibits referenced throughout this decision correspond to the exhibit list cited in BIS' post-hearing brief.

In addition to the citation issue, some of the exhibits cited by BIS in the post-hearing brief raise the question of admissibility. For example, BIS relies on testimony taken during the February 6, 2018 hearing before CALJ Brudzinski. This was in error. As discussed above, CALJ Brudzinski lacked authority to convene the hearing on February 6, 2018, and similarly lacked authority to place any witnesses under oath, because he was not authorized to exercise the powers of an inferior officer at the time. Since he lacked authority to place witnesses under oath or convene the hearing, any testimony before CALJ Brudzinski should not be considered. To hold otherwise would sidestep *Lucia's* instruction to grant a respondent a new hearing where an ill-appointed ALJ has presided before. Indeed, it would be an odd outcome to allow a respondent to have a new hearing because the first ALJ was wrongfully appointed, but allow all the testimony presented to that same ALJ as evidence in a second hearing. Accordingly, the undersigned will strike Exhibit 5 and will not consider the February 6, 2018 transcript in this case.

With regard to Exhibit 8, which is the transcript of the proceedings on June 11, 2019, the undersigned finds it a bootless errand and a waste of resources to attach the hearing transcript as an exhibit. The undersigned's July 11, 2019 Order serving the transcript on the parties made the document a part of the record. As a matter of housekeeping, by attaching it as an exhibit, BIS clutters the record and creates redundant copies of identical documents for no reason. Accordingly, Exhibit 8 is stricken; however, the undersigned will rely on the substance of the transcript, cited as Tr. at ____.

Lastly, there is the issue of an affidavit signed by BIS' counsel. A review of Exhibit No. 27 shows it is a sworn statement created on August 15, 2019, well after the hearing in this case. BIS attached this exhibit without permission of the ALJ. Given the timing of its creation, and the fact that BIS seeks to add evidence into the record without any regard for the ALJ as the evidentiary gatekeeper in this case, I am striking Exhibit 27, and will not rely on it in this decision.

b. B. Respondents' Attachments

A review of Respondents' post-hearing brief shows Attachments 1 and 2 are documents which purportedly support the argument concerning Respondents' inability to pay a sanction if one is imposed in this case. Without belaboring this issue, the undersigned will strike both attachments. A review of the hearing transcript in this case shows the undersigned granted BIS' motion to prevent Respondents from raising an inability to pay argument during these proceedings because of Respondents' discovery violations, *i.e.,* failure to comply with the May 22, and 24, 2019 Orders. Tr. at 12.[18]

Having disposed of these evidentiary issues, the undersigned turns to the case at bar.

Recommended Findings of Fact

Upon review of the file, the undersigned finds the following facts proved by preponderant evidence:

1. On or about July 12, 2011, Reflect Geophysical obtained a license from BIS covering certain seismic survey equipment, including compass birds and streamer sections (survey equipment). Ex. 7.

2. At some point after Reflect Geophysical obtained the license, Respondent Nordic came into possession of the survey equipment. Ex. 14.

3. Respondent Nordic is a company located in Singapore, and at all times relevant to this case, Morten Innhaug was the Chairman and majority shareholder of Nordic Maritime Pte. Ltd. Ex. 3.

4. On or about April 11, 2012, Reflect Geophysical provided Respondent

[18] BIS also asked the undersigned to find, as a result of the discovery violation, that Respondent Innhaug allegedly received 90 percent of a $22.8 million distribution. Tr. at 14. The undersigned finds it unnecessary to make such a finding because Respondents' ability to pay is no longer a question in this case since I prohibited Respondents from raising the issue as a mitigating factor.

Nordic with a cease and desist letter, warning the equipment's use in Iranian waters would violate the license BIS granted Reflect Geophysical. The letter also demanded Respondent Nordic return the equipment until resolution of the dispute. Ex. 14; Tr. at 71.

5. On April 17, 2012, Reflect Geophysical informed BIS Respondent Nordic might use the survey equipment to explore oil and gas in Iran, in violation of U.S. law and regulation. Ex. 11.

6. In June 2012, after the cease and desist letter, Reflect Geophysical leased the survey equipment to Respondent Nordic pursuant to a written agreement, which included a retroactive commence date of April 2012. Ex. 16.

7. Although Respondents had a lease to use the survey equipment, Respondents never obtained any licenses from BIS for possession, use, or reexport of the leased survey equipment. Ex. 4.

8. On or about May 1, 2012, through and including April 4, 2013, Respondent Nordic transported the survey equipment to the Forouz B natural gas field and used it to conduct seismic surveys. Ex. 4.

9. The Forouz B natural gas field is within Iranian territorial waters. Ex. 4.

10. Respondent Nordic transported the survey equipment to the Forouz B natural gas field aboard the M/V ORIENT EXPLORER, a vessel it leased/chartered from a Russian state-owned company, DMNG, via a charter party signed by Respondent Innhaug. Ex. 4.

11. Respondent Nordic conducted the seismic survey of the Forouz B natural gas field pursuant to an €11.8 million euro contract it had with Mapna International FZE (Mapna), using the survey equipment at issue in this case. Ex. 4; Ex. 13; Tr. at 15.

12. Mapna has significant ties to Iran. Tr. at 64.

13. Respondents neither sought nor obtained authorization from either BIS or the Department of Treasury's Office of Foreign Assets Control (OFAC) to reexport the survey equipment at issue to the Forouz B natural gas field in Iran. Ex. 6.

14. Respondents were aware the survey equipment would be used to conduct a seismic survey at the Forouz B natural gas field in Iran. Ex. 4.

15. Respondents were on notice that U.S. government authorization was required to reexport the survey equipment to Iran, including the territorial waters of Iran. Ex. 14; Tr. at 71–72.

16. On April 15, 2014, Respondent Nordic, through its Chief Executive Officer, Kjell Goran Gauksheim, provided BIS a written submission falsely stating that Reflect Geophysical: (1) Never advised Respondent Nordic that the survey equipment was subject to a BIS export license; (2) never communicated any BIS export license conditions controlling the survey equipment; and (3) never provided a copy of the BIS license (granted to Geophysical) to Respondents. Tr. at 66; Ex. 4.

Discussion

c. A. Jurisdiction

At the time of the alleged offenses, BIS had jurisdiction over this matter pursuant to the Export Administration Act of 1979 (EAA), 50 U.S.C. 4601–4623, specifically the regulations promulgated under that Act. *See* 15 CFR 730–774. Although the EAA of 1979 had lapsed at the time, the President of the United States was authorized to enforce the regulations promulgated under the EAA of 1979 pursuant to the International Emergency Economic Powers Act (IEEPA). 50 U.S.C. 1701, *et seq.*

In August 2018, Congress passed the Export Control Reform Act of 2018 and repealed much of the EAA. Under the 2018 Act, Congress provided BIS with permanent statutory authority to administer the export regulations. 50 U.S.C. 4826 (EAR in effect on August 13, 2018, shall continue in effect). The 2018 Act specifically notes that all administrative actions made or administrative proceedings commenced are not disturbed by the new legislation. *See* 50 U.S.C. 4826. Accordingly, BIS has jurisdiction over this matter, as it did at the time of the offenses in question.

d. B. Burden of Proof

As set forth in prior BIS Decisions and Orders, BIS must prove the allegations in the charging letter by reliable, probative, and substantial evidence. *In the Matter of Ihsan Medhat Elashi,* 71 FR 38843, 38847 (July 10, 2006) *citing* 5 U.S.C. 556(d). In *Elashi,* the ALJ acknowledged the Supreme Court's traditional ''preponderance of the evidence'' standard of proof applies to BIS proceedings. *Id. citing Dir., Office of Workers' Comp. Programs* v. *Greenwich Collieries,* 512 U.S. 267, 290 (1994) (the preponderance of the evidence . . . applies in adjudications under the Administrative Procedure Act) (*citing Steadman* v. *SEC.,* 450 U.S. 91 (1981)).

Ultimately, to prevail, BIS must establish that it is more likely than not the Respondents committed the violations alleged in the charging letters. *See Herman & Maclean* v. *Huddleston,* 459 U.S. 375, 390 (1983). In other words, the agency must demonstrate ''that the existence of a fact is more probable than its nonexistence.'' *Concrete Pipe & Products* v. *Construction Laborers Pension Trust,* 508 U.S. 602, 622 (1993). To satisfy the burden of proof, BIS may rely on direct and/or circumstantial evidence. *See generally Monsanto Co.* v. *Spray-Rite Servo Corp.,* 465 U.S. 752, 764–765 (1984); *In the Matter of BiB and Malte Mangelsen,* 71 FR 37042, 37047 (June 29, 2006).

With this burden in mind, the undersigned turns to the charges in this matter.

e. C. Charging Letters

The charging letters in this case allege separate violations against Respondent Nordic and Respondent Innhaug. A review of the charges shows they are not in logical order and difficult to follow. As noted by BIS' brief, the charges are more easily analyzed out of order because Charge 2 relates to the underlying action and forms the basis of the other charges. Accordingly, I will address Charge 2 first, followed by Charge 1 and Charge 3 against Respondent Nordic, and finally address Charge 1 against Respondent Innhaug.

1. Charge 2 Against Respondent Nordic—Reexporting Equipment to Iran

In Charge 2 of the Nordic Charging Letter, BIS alleges Respondent Nordic violated section 764.2(a) by reexporting U.S.-origin survey equipment to Iran without the required license. Respondent Nordic admits it reexported the survey equipment without a license, but denies it had knowledge that reexporting to Iranian waters violated the license requirement. *See* Answer, Ex. 6. As set forth below, I find BIS proved by preponderant evidence Respondent Nordic violated 15 CFR 764.2(a) by reexporting the survey equipment at issue in this case.

As a general, overarching rule, 15 CFR 764.2(a) prohibits all violations of the EAR. Violations of 15 CFR 764.2(a) are strict liability offenses, and BIS need not show a violator intentionally, knowingly committed the violations. *See In the Matter of Wayne LaFleur,* 74 FR 5916, 5918 (February 3, 2009).

In 2012–2013, at the time of the alleged offense, the EAR strictly prohibited reexports of certain equipment identified on the Commerce Control List (CCL). 15 CFR Supp. No. 1 to Part 774. However, the EAR did not close the door to all reexportation of CCL items; instead, it permitted an individual to request a license from the U.S. government, which would allow

the reexport. 15 CFR 742.4, 742.8, and 746.7 (2012–2013). But reexporting any of the items on the CCL without the appropriate license, constitutes an EAR violation under 15 CFR 764.2(a) and non-compliance with 15 CFR 742.4, 742.8, 746.7, and 15 CFR Supp. No. 1 to Part 774.

A review of the CCL shows the survey equipment at issue here was clearly classified under Export Control Classification Number (ECCN) 6A001; neither party contests this point. 15 CFR Supp. No. 1 to Part 774. Similarly, the parties agree Respondent Nordic possessed the survey equipment without a license and that Respondent Nordic reexported the equipment for use in Iranian waters onboard the M/V ORIENT EXPLORER. Exs. 4; 6; 9; 11. Exhibit 6 shows Respondent Nordic admitted to using the survey equipment in Iranian waters.

There can be only one conclusion under the facts of this case, by taking the equipment into Iranian waters and conducting a seismic survey without a license, Respondent Nordic violated 15 CFR 764.2(a) by engaging in conduct prohibited by 15 CFR 742.4, 742.8, 746.7, and 15 CFR Supp. No. 1 to Part 774.

Respondent Nordic's argument that it did not know of the licensure requirement is unpersuasive. As noted above, it is irrelevant whether a violator knows a license is required because these types of violations are strict liability offenses. Ergo, Respondent Nordic's lack of regulatory knowledge is not a defense to this specific charge. *In the Matter of Wayne LaFleur,* 74 FR 5916, 5918 (February 3, 2009).

2. Respondent Nordic Charge 1—Acting With Knowledge of EAR Violation

Unlike Charge 2, Charge 1 alleges Respondent Nordic not only reexported the survey equipment, but did so *with knowledge* that the reexport would violate the regulations and licensure requirements. *See* 15 CFR 764(e) (emphasis added). As noted above, Respondent Nordic acknowledges it reexported the survey equipment, but insists it did so without knowledge of the EAR violations.

Pursuant to 15 CFR 764.2(e), no person may act with knowledge they are undertaking an action in violation of the EAR. The regulations define knowledge as:

> not only positive knowledge that the circumstance exists or is substantially certain to occur, but also an awareness of a high probability of its existence or future occurrence. Such awareness is inferred from evidence of the conscious disregard of facts known to a person and is also inferred from a person's willful avoidance of facts.

15 CFR 772.1. Thus, where BIS alleges a section 764.2(e) violation, BIS must prove (1) the person violated the regulations; and (2) the violator did so with scienter—knowledge. A lack of knowledge would be a defense under this charge.

As set forth above, the parties do not dispute whether Respondent Nordic violated the EAR when it reexported the survey equipment to Iranian waters. Thus, the record proves the first element of a section 764.2(e) violation.

With regard to the second element, the record shows Respondent Nordic had the requisite knowledge when it violated the regulations. Specifically, Respondent Nordic acknowledges in April 2012, Reflect Geophysical straightaway warned Respondent Nordic by a cease and desist letter that use of the survey equipment in Iranian waters would violate the license BIS granted. Ex. 14. And while it may seem odd that Reflect Geophysical subsequently leased the equipment to Respondent Nordic in June 2012, the record shows Reflect Geophysical provided Respondent Nordic with a copy of the license granted by BIS as part of the June 2012 lease. The license attached to the lease specifically identifies countries wherein the equipment may be used, and Iran is noticeably absent. Ex. 7. Thus, Respondent Nordic had two clear notices informing it of the clear illegality of using the survey equipment in Iranian waters and chose, on both instances, to ignore the warnings.

The evidence is conclusive. Respondent Nordic had actual specific knowledge that use of the equipment in Iranian waters would run awry of U.S. law and regulations. Accordingly, I find BIS proved Respondent Nordic violated 15 CFR 764(e), by knowingly violating 15 CFR 764.2(a), 15 CFR 742.4, 742.8, 746.7, and 15 CFR Supp. No. 1 to Part 774.

Even assuming, arguendo, Respondent Nordic did not have actual specific knowledge that it was violating the EAR, Respondent Nordic did have an awareness of a high probability that BIS restrictions applied to use of the equipment in Iranian waters, and that the use would be a regulatory violation. 15 CFR 772.1. The record shows not only did Respondent Nordic receive a cease and desist letter, but Respondent Nordic and Reflect Geophysical had an ongoing dispute about the equipment's use. A review of the April 14, 2012 cease and desist letter shows Respondent Nordic had a history of conflict with Reflect Geophysical, as expressed in Paragraph 5 which reads:

> For the foregoing reasons we HEREBY DEMAND that . . . Nordic take steps to have the Vessel returned to Singapore so that Equipment may be offloaded and stored at mutually acceptable location, as previously suggested in our letters 7 and 21 March 2012 pending the resolution of this dispute. . . .

Ex. 14 (emphasis in original). It bears repeating, after sending the cease and desist letter, Reflect Geophysical again provided Respondent Nordic with clear information concerning the illegality of the survey equipment's use in the June 2012 lease. And although it may seem highly irresponsible for Reflect Geophysical to subsequently lease the equipment to Respondent Nordic in June 2012, the fact remains the lease included a copy of the BIS license describing restrictions applicable to the equipment. This license makes very clear the countries in which the equipment may be reexported, and Iran is not on the list.

These communications between Respondent Nordic and Reflect Geophysical are telling and lead to the conclusion that the parties discussed use of the equipment in Iranian waters. To this end, it is far more likely than not that Respondent Nordic simply ignored all warnings against use of the equipment in Iranian waters and proceeded with a knowing disregard for the restrictions.

Upon review of the record, and applying the EAR to the case at hand, preponderant evidence shows Respondent Nordic possessed the requisite knowledge contemplated under 15 CFR 764.2(e) when it violated the EAR. BIS supplied ample evidence proving Respondent Nordic knew reexportation of the survey equipment into Iranian waters was a violation of the regulations.

3. Respondent Nordic Charge 3—Making False and Misleading Statements

In Charge 3, BIS alleges Respondent Nordic made false and misleading statements while BIS investigated the use of the survey equipment in this case. *See* 15 CFR 764.2(g). The record shows BIS proved Charge 3.

Title 15 CFR 764.2(g) prohibits misrepresentation and concealment of facts, and provides in pertinent part:

> (1) No person may make any false or misleading representation, statement, or certification, or falsify or conceal any material fact, either directly to BIS, the United States Customs Service, or an official of any other United States agency, or indirectly through any other person:

(i) In the course of an investigation or other action subject to the EAR. . . .

Where a corporation is involved, an officer or employee constitute the acts of the corporation. *See U.S.* v. *Sain,* 141 F.3d 463 (3d Cir. 1998); *S.E.C.* v. *Koenig,* 2007 WL 1074901 *6 (N.D. Ill. Apr. 5, 2007).

Applying section 764.2(g) here, BIS must prove (1) BIS was conducting an ongoing investigation; and (2) during the investigation, Respondent Nordic made the false or misleading statements.

A review of the record shows BIS opened an investigation after receiving Reflect Geophysical's April 17, 2012 letter expressing concern that Respondent Nordic might use the survey equipment in Iranian waters. Tr. at 38. Moreover, Respondent Nordic's April 15, 2014 letter to BIS shows Respondent Nordic's awareness of the ongoing BIS investigation, inasmuch as the letter cites ''potential non-compliance'' and an interview with Special Agent Payton from the Office of Export Enforcement's (OEE) Houston, Texas office. Ex. 4. Accordingly, BIS proved at some time between April 17, 2012, and April 15, 2014, BIS opened an investigation concerning the use of the survey equipment.

The April 15, 2014 letter is also the source of BIS' theory that Respondent Nordic made false and/or misleading representations to BIS during the investigation. Specifically, the April 15, 2014 letter from Respondent Nordic's CEO,[19] accuses Reflect Geophysical of: (1) Never advising Respondent Nordic that the survey equipment was subject to a BIS export license; (2) never communicating any BIS export license conditions controlling the survey equipment; and (3) never providing a copy of the BIS license (granted to Geophysical) to Respondent Nordic. Ex. 4; Tr. at 66. None of these statements were true.

As noted above, the evidence shows Respondent Nordic received the cease and desist letter in April 2012, directly referencing the BIS license and the restrictions on the equipment's use in Iranian waters. Second, the June 2012 lease agreement included a copy of the license which expressly stated the conditions controlling the survey equipment. These two documents prove it is more probable than not Respondent Nordic, through its CEO, misled BIS or made false misrepresentations to BIS during the course of an investigation when it sent the April 15, 2014 letter to BIS. Accordingly, I find BIS proved Charge 3 against Respondent Nordic.

4. Respondent Innhaug Charge 1—Causing, Aiding, and Abetting Any Act Prohibited by the EAR

In Charge 1, BIS makes a separate allegation against Respondent Innhaug, and alleges he caused, aided, or abetted Respondent Nordic to reexport maritime surveying equipment into Iranian waters. Pursuant to BIS case precedent and the applicable regulations, I find BIS proved Charge 1 against Respondent Innhaug.

Title 15 CFR 764.2(b) provides: No person may cause or aid, abet, counsel, command, induce, procure, or permit the doing of any act prohibited, or the omission of any act required, by the EAA, the EAR, or any order, license or authorization issued thereunder. Where a corporation is involved, an officer or employee can be charged with aiding and/or abetting the corporation's underlying violations. *See U.S.* v. *Sain,* 141 F.3d 463 (3d Cir. 1998); *S.E.C.* v. *Koenig,* 2007 WL 1074901 *6 (N.D. Ill. Apr. 5, 2007). As explained in *Koenig,* an agent's actions can constitute both proof of a company's primary violations and proof of the agent's aiding and abetting violations. BIS case precedent also shows under the EAR, a corporate officer can be held liable for the acts committed in helping the corporation violate the EAR. In *In the Matters of: Trilogy International Assoc., Inc., and William Michael Johnson,* the Under Secretary agreed that an agent who (1) directs and controls operations of a corporation; and (2) takes one or more specific actions in connection with an EAR violation, may be held liable for underlying violations committed by the company. 15–BIS–0005 (2018).

Here, BIS claims Respondent Innhaug, as the Chairman and majority shareholder, caused, aided, and abetted Respondent Nordic's unlicensed reexports of the survey equipment into Iranian waters. Having already determined Respondent Nordic reexported the survey equipment into Iranian waters in violation of the EAR, the only question remaining is whether Respondent Innhaug aided and abetted in this conduct.

In this case, the primary evidence against Respondent Innhaug comes from the time charter party[20] entered into on or about April 1, 2012. Ex. 12. The time charter party bears Respondent Innhaug's and a DMNG representative's signature. The essence of the agreement is for worldwide use of the M/V ORIENT EXPLORER, which, as the evidence shows, was the vessel used to reexport the survey equipment into Iranian waters. Indeed, securing the vessel to carry the equipment to Iranian waters was an integral part of the ultimate violation. Therefore, it goes without saying that the agreement was essential to reexporting the equipment to Iran in violation of the EARs.[21]

Moreover, the record shows the April 11, 2012 cease and desist letter was addressed to and at the attention of Respondent Innhaug, and Respondent Innhaug admitted to receiving the letter. Ex. 14; Ex 15. Respondent Innhaug also admitted, through the course of discovery, to reviewing the April 15, 2014 submission to BIS, wherein Respondent Nordic, through the signature of another officer, made the three false, misleading statements set forth in Charge 3, discussed above. Ex. 9 at para. 33–35.

Accordingly, I find Respondent Innhaug aided and abetted Respondent Nordic in the abovementioned EAR violations and therefore violated 15 CFR 764.2(b).

Recommended Sanction

Having determined Respondents committed the abovementioned violations, I now turn to the appropriate sanction to recommend in this case. Section 764.3 of the EAR permits the undersigned to recommend: (1) A civil penalty, (2) a denial of export privileges under the regulations, and (3) an exclusion from practice. *See* 15 CFR 764.3. Pursuant to 50 U.S.C. 1705, which was in effect at the time of the offense, the undersigned may impose a civil penalty in an amount that is twice the amount of the transaction that is the basis of the violation with respect to which the penalty is imposed.

Additionally, Supplement No. 1 to 15 CFR part 766 is instructive in that it provides guidance to BIS on how to make penalty determinations during administrative enforcement

[19] Courts roundly recognize that a corporate officer's conduct constitute acts of the corporation itself. *See S.E.C. Koenig,* 2007 WL 1074901 noting that a corporation's agent's action can constitute proof of a corporation's violation.

[20] A time charter party is a maritime contract for use of a vessel for a certain period of time. *See Interocean Shipping Co.* v. *M/V LYGARIA,* 512 F. Supp. 960, 967 (D. Md. 1981) (noting ''[a] time charter party is simply an agreement between a vessel owner and a charterer that the latter may use the vessel's cargo carrying capacity to transport unspecified cargos for a fixed period of time.'')

[21] The undersigned observes that Respondent Innhaug's entrance into the time charter party agreement appears to be well before the cease and desist letter was sent to Respondent Innhaug. However, as noted above, knowledge is not an element under Charge 2. Therefore, Respondent Innhaug may have unknowingly aided and abetted his company in violating the EAR in April 2012 by entering into the charter party, which he knew was for use in Iranian waters under the Mapna agreement.

''settlement'' cases.[22] Even though this case is not a settlement, the information contained in Supplement No. 1 can assist in determining the appropriate sanction.

Supplement No. 1 discusses specific mitigating and aggravating factors. The mitigating factors include:

1. The party self-disclosed the violations (given great weight).
2. The party created an effective export compliance program (given great weight).
3. The violations resulted from a good-faith misinterpretation.
4. The export would likely have been granted upon request.
5. The party does not have a history of past export violations.
6. The party cooperated to an exceptional degree during the investigation.
7. The party provided substantial assistance in the BIS investigation.
8. The violation did not involve harm of the nature the regulations were intended to protect.
9. The party had little export experience and was not familiar with the requirement.

15 CFR part 766, Supp No. 1, at § III(B)

The eight aggravating factors include:

1. The party deliberately hid the violations (given great weight).
2. The party seriously disregarded export responsibilities (given great weight).
3. The violation was significant in view of the sensitivity of the item or destination (given great weight).
4. The violation was likely to involve harm of the nature the regulations intended to protect.
5. The value of the exports was high, resulting in a need to serve an adequate penalty for deterrence.
6. Other violations of law and regulations occurred.
7. The party has a history of past export violations.
8. The party lacked a systematic export compliance effort.

Id. I address each in turn.

f. A. Mitigating Factors

1. The party self-disclosed the violations (given great weight).

The record shows Respondent Nordic did provide a self-disclosure on April 15, 2014. From the broadest perspective, Respondent Nordic should be applauded for doing so. However, as discussed above, the disclosure contained blatant falsehoods that Respondents knew, or should have known about. Indeed, this disclosure forms the basis of Charge 3, where BIS proved Respondent Nordic made false and misleading statements.

Accordingly, although this is typically a mitigating factor, the undersigned finds any mitigation normally attributed to self-disclosure is nullified by the unique facts of this case.

2. The party created an effective export compliance program (given great weight).

There is some evidence in the record showing Respondents created an export compliance program as a result of the abovementioned incident. Ex. 4. Respondents' April 15, 2014 self-disclosure indicates the company hired outside counsel to address compliance issues, restructured management, and arranged training, among other actions. I find these steps do not rise to an export compliance program that would address the violations in this case. Here, Respondents actions were not the result of a lapse in or the existence of a compliance program, but instead were the result of blatant knowing disregard for U.S. law. To this end, a compliance program, even if put in place, would have little effect on deliberate, intentional violations, such as misleading BIS and knowingly violating the regulations. To this end, I find this factor not mitigating.

3. The violations resulted from a good-faith misinterpretation.

The record shows Respondents' conduct did not result from a good faith misinterpretation. Although Respondents argued the license issued to Reflect Geophysical was unclear as to how it applied to Iranian waters, the record belies Respondents' argument. Respondents had two opportunities to review the license, first when explained through the cease and desist letter in April 2012, and second, when Reflect Geophysical (despite knowing Respondents, at one time, might use the equipment in violation of the license) provided a copy of the license to Respondents as part of leasing the equipment.

This is not a case of misinterpretation at all; nothing in the license or the cease and desist letter is ambiguous. Both make clear using the survey equipment in Iranian waters would be contrary to U.S. law.

4. The export would likely have been granted upon request.

During the hearing, BIS presented testimony indicating it would not have granted the request to use the equipment in Iranian waters. Tr. at 146–147. Respondents provided no evidence, given their absence at the hearing, and no evidence throughout this proceeding that BIS might have granted their request to reexport the survey equipment to Iranian waters. Accordingly, this factor is not mitigating.

5. The party does not have a history of past export violations.

The record contains no evidence concerning prior export violations. As neither party provided evidence in this regard, it is neither aggravating nor mitigating and given no weight.

6. The party cooperated to an exceptional degree during the investigation.

The record shows Respondents made farcical attempts to cooperate with BIS in this case. Specifically, as noted above, Respondents made a self-disclosure concerning reexport of the survey equipment in this case. However, that disclosure included falsehoods and misrepresentations. Accordingly, it cannot be considered cooperation under the facts of this case and is not mitigating.

7. The party provided substantial assistance in the BIS investigation.

There is no evidence Respondents gave substantial assistance to BIS during its investigation. Accordingly, this factor is not mitigating.

8. The violation did not involve harm of the nature the regulations were intended to protect.

The violation in this case goes to the very heart of the EAR's purpose. As part of our national security, BIS stringently regulates certain equipment which it identifies by regulations and the **Federal Register**. In 2012–2013, at the time of the alleged offense, the EAR strictly prohibited reexports of certain equipment identified on the CCL, which included the survey equipment at issue in this case. 15 CFR Supp. No. 1 to Part 774. These materials are controlled due to national security concerns, meaning the materials could make a significant contribution to the military potential of certain countries, like Iran. Tr. at 89. Moreover, BIS controls this equipment for anti-terrorism purposes inasmuch as access to this equipment could help a country develop a capacity to either support an international terrorist group or engage in terrorist activities on their own. Tr. at 89. Seismic surveys find oil and gas, oil and gas make money. Respondents' conduct here could conceivably help fund terrorist groups in Iran, particularly since the evidence shows the contract to conduct the survey was at the behest of Mapna, a company with deep ties to Iran.

In this case, Respondents did exactly what the regulations attempted to prevent, the use of this equipment to survey waters controlled by a U.S. adversary, Iran. Accordingly, this factor is not mitigating.

[22] Several updates have been made to Supplement No. 1 of 15 CFR part 766. As the last violation charged ended in 2014, we are using the January 29, 2014 to July 21, 2016 version of Supplement No. 1. The earlier version of Supplement No. 1 (June 4, 2010 to January 28, 2014) used the same aggravating/mitigating factors.

9. The party had little export experience and was not familiar with the requirement.

The record shows some evidence Respondents were familiar with U.S. export laws. A review of Exhibit 17 shows Respondents had a history of dealing with a similar maritime survey equipment license before. To this end, I find Respondents were somewhat familiar with U.S. regulations on the issue, and therefore this factor is not mitigating.

g. B. Aggravating Factors

1. The party deliberately hid the violations (given great weight).

As discussed above in Charge 3, the record contains evidence proving Respondents misled BIS investigators by making false statements concerning their receipt of the survey equipment lease and their understanding of how use of the survey equipment in Iranian waters might violate U.S. law. Inherently, Charge 3 could be construed as ''deliberately hiding'' evidence of the violation. Failing to admit they received a copy of the lease, and/or that they knew of the Iranian restrictions could easily be described as ''hiding the truth.'' However, aside from the misleading statements in the self-disclosure, there does not appear to be any other evidence that Respondents hid any information from BIS. Accordingly, this factor is not aggravating outside of the inherent offense outlined in Charge 3.

2. The party seriously disregarded export responsibilities (given great weight).

This case is the quintessential example of disregarding export responsibilities. Given the documentary evidence Respondents were provided with, the advanced notice of their potential violation in the April 2012 cease and desist letter, and the fact they received a copy of the license restricting the survey equipment's use, the undersigned is compelled to find Respondents egregiously disregarded their export responsibilities. The facts concerning this aggravating factor are substantial and given great weight.

3. The violation was significant in view of the sensitivity of the item or destination.

I find this factor not applicable and therefore given no weight.

4. The violation was likely to involve harm of the nature the regulations intended to protect.

The nature of the regulations here intend to control the survey equipment and prevent its use by U.S. adversaries. Here, the record shows Respondents not only used the equipment in Iranian waters, a notorious U.S. adversary, but also shows that they did so pursuant to a contract entered into with Mapna, a company with ties to Iran. Tr. at 64. Accordingly, Respondents' actions committed the very evil the U.S. regulations hoped to prevent. This factor is aggravating.

5. The value of the exports was high, resulting in a need to serve an adequate penalty for deterrence.

In this case, the specific value of the equipment exported to Iranian waters is not relevant; however, the value of the survey equipment's use to survey oil and gas in Iranian waters is. In fact, the evidence in this case shows Respondents use of the equipment resulted from a lucrative contract between Respondent Nordic and Mapna, to the tune of €11.8 million euros. Ex. 13. Respondents knew their use of the equipment would lead to consequences, but given the value of the Mapna contract, they found 11.8 million reasons to ignore U.S. law. To this end, the undersigned can only conclude lucre, cupidity, and avariciousness propelled Respondents' conduct.

Because Respondents' illegal use of the equipment led to such a profitable contract, the penalty should be such that it dissuades further violations of this sort, and act as a strong deterrent against this type of behavior. This factor is aggravating.

6. *Other violations of law and regulations occurred.*

The record contains no evidence of other violations of law, other than those discussed above. But given Respondents' conduct involves not only a knowing violation, but a violation resulting from misleading BIS, I conclude this factor is aggravating.

Upon reviewing all the factors in this case, and considering the record as a whole, I find a sanction in the amount of €23.6 million euros is appropriate. This amount is commensurate to two times the value of the contract Respondents had with Mapna. This sanction is appropriate not only because it is commensurate with the offense given Respondents' assistance to a U.S. adversary, but it also serves to deter future conduct by Respondents and others.[23]

Ultimately, any company presented with a contract requiring the company to violate U.S. law, should not be able to build into the contract the possible penalties resulting from a BIS civil penalty action. Accordingly, the only way to deter companies from building in the civil penalty into the contract's value is to make the penalty so high that the contract to violate U.S. law becomes not only non-profitable, but detrimental. To this end, by fining Respondents double the amount they would have earned in the Mapna contract, BIS is able to dissuade companies from considering contracts requiring the violation of U.S. law as a foreseeable cost factored into the contract's value.

Therefore, Respondents shall be assessed a fine in the amount of €23.6 million euros, or $31,425,760.00 U.S. dollars.[24] The fine is joint and severally imposed on both Respondents.

BIS also asks the undersigned to recommend an order denying Respondents' export privileges for fifteen years. I believe a denial order set to a fixed period of time is inappropriate for this case. Instead, the undersigned recommends the Under Secretary deny Respondents' export privileges until the fine set forth above is paid in full. By doing so, the Under Secretary encourages prompt payment of the fine and provides Respondents with an ability to show rehabilitation.

VI. Recommended Order

It is hereby recommended, respondents shall jointly and severally be liable to pay a civil penalty in the amount of $31,425,760.00 U.S. dollars.

It is further recommended, a denial of U.S. export privileges shall persist against *Respondents Nordic Maritime Pte. Ltd.*, 3 HarbourFront Place, #04–03 HarbourFront Tower 2, Singapore 099254 and Morten Innhaug, 16 Keppel Bay Drive, #04–20 Caribbean at Keppel Bay, Singapore 098643 until the fine in this case is satisfied in full. In accordance with 15 CFR Supplement No. 1 to Part 764, the recommended terms of the export privileges denial against Respondents Nordic Maritime Pte. Ltd., 3 HarbourFront Place, #04–03 HarbourFront Tower 2, Singapore 099254 and Morten Innhaug, 16 Keppel Bay Drive, #04–20 Caribbean at Keppel Bay, Singapore 098643, is as follows:

First, that until the abovementioned fine is paid, Respondents Nordic Maritime Pte. Ltd., 3 HarbourFront Place, #04–03 HarbourFront Tower 2, Singapore 099254 and Morten Innhaug,

[23] The aggravating factors in 7 and 8 are discussed in the mitigating factors 2 and 5 above.

[24] BIS asks the undersigned to impose a fine of 11.8 million euros, and asks the undersigned to convert that amount to U.S. dollars based on the exchange rate on May 1, 2012—the date which Respondent Nordic began conducting the survey in Iran. I find the more appropriate conversion date to be March 2012, the date which Respondent Nordic entered into a contract with Mapna. Ex. 13. However, because the Mapna contract does not have a specific day, the undersigned will use March 1, 2012, as the date for conversion. *See https://markets.businessinsider.com/currency-converter/euro_united-states-dollar.*

16 Keppel Bay Drive, #04–20 Caribbean at Keppel Bay, Singapore 098643, and all of their successors or assigns, when acting for or on behalf of them, their agents, and employees, and their successors or assigns (Denied Persons) may not, directly or indirectly, participate in any way in any transaction involving any commodity, software or technology (hereinafter collectively referred to as ''item'') exported or to be exported from the United States that is subject to the Regulations, or in any other activity subject to the Regulations, including, but not limited to:

A. Applying for, obtaining, or using any license, License Exception, or export control document;

B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or in any other activity subject to the Regulations; or

C. Benefiting in any way from any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or in any other activity subject to the Regulations.

Second, that no person may, directly or indirectly, do any of the following:

A. Export or re-export to or on behalf of the Denied Persons any item subject to the Regulations;

B. Take any action that facilitates the acquisition or attempted acquisition by the Denied Persons of the ownership, possession, or control of any item subject to the Regulations that has been or will be exported from the United States, including financing or other support activities related to a transaction whereby the Denied Persons acquire or attempt to acquire such ownership, possession or control;

C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from the Denied Persons of any item subject to the Regulations that has been exported from the United States;

D. Obtain from the Denied Persons in the United States any item subject to the Regulations with knowledge or reason to know that the item will be, or is intended to be, exported from the United States; or

E. Engage in any transaction to service any item subject to the Regulations that has been or will be exported from the United States and that is owned, possessed or controlled by the Denied Persons, or service any item, of whatever origin, that is owned, possessed or controlled by the Denied Persons if such service involves the use of any item subject to the Regulations that has been or will be exported from the United States. For purposes of this paragraph, servicing means installation, maintenance, repair, modification or testing.

Third, that after notice and opportunity to oppose such action as provided in Section 766.23 of the Regulations, any person, firm, corporation, or business organization related to the Denied Persons by affiliation, ownership, control, or position of responsibility in the conduct of trade or related services may also be made subject to the provisions of this Order.

Fourth, that this Order does not prohibit any export, reexport, or other transaction subject to the Regulations where the only items involved that are subject to the Regulations are the foreign-produced direct product of U.S.-origin technology.

This Recommended Decision and Order is being referred to the Under Secretary for review and final action by overnight carrier as provided under 15 CFR 766.17(b)(2). Due to the short period of time for review by the Under Secretary, all papers filed with the Under Secretary in response to this Recommended Decision and Order must be sent by personal delivery, facsimile, express mail, or other overnight carrier as provided in 15 CFR 766.22(a).

Submissions by the parties must be filed with the Office of the Under Secretary for Export Administration, Bureau of Industry and Security, U.S. Department of Commerce, Room H–3898, 14th Street and Constitution Avenue NW, Washington, DC 20230, within twelve (12) days from the date of issuance of this Recommended Decision and Order. Thereafter, the parties have eight (8) days from receipt of any responses in which to submit replies. *See* 15 CFR 766.22(b).

Within thirty (30) days after receipt of this Recommended Decision and Order, the Under Secretary shall issue a written order, affirming, modifying, or vacating the Recommended Decision and Order. *See* 15 CFR 766.22(c).

Accordingly, I am referring this Recommended Decision and Order to the Under Secretary for review and final action for the Agency, as provided in 15 CFR 766.22.

Done and dated February 7, 2020, at Galveston, Texas.

Dean C. Metry,

Administrative Law Judge, United States Coast Guard.

Certificate of Service

I hereby certify that I have served the foregoing document as indicated below to the following parties:

Cordell A. Hull, Acting Under Secretary of Commerce for Industry and Security, Bureau of Industry and Security, U.S. Department of Commerce, Room 3896, 1401 Constitution Ave. NW, Washington, DC 20230, Sent by Federal Express.

EAR Administrative Enforcement Proceedings, U.S. Coast Guard, ALJ Docketing Center, Attn: Hearing Docket Clerk, 40 S. Gay Street, Room 412, Baltimore, MD 21202–4022, Sent electronically: *aljdocketcenter@uscg.mil*.

Gregory Michelsen, Esq., Zachary Klein, Esq., Attorneys for Bureau of Industry and Security, Office of Chief Counsel for Industry and Security, U.S. Department of Commerce, 14th Street & Constitution Avenue NW, Room H–3839, Washington, DC 20230, Sent by Federal Express.

Douglas N. Jacobson, Esq., JACOBSON BURTON KELLEY PLLC, 1725 I Street NW, Suite 300, Washington, DC 20006, Sent by Federal Express.

Done and dated February 7, 2020, at Galveston, Texas.

Janice M. Emig,

Paralegal Specialist, United States Coast Guard, Department of Homeland Security.

[FR Doc. 2020–05600 Filed 3–17–20; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–028]

Hydrofluorocarbon Blends From the People's Republic of China: Affirmative Final Determination of Circumvention of the Antidumping Duty Order; Unfinished R-32/R-125 Blends

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that imports of unfinished blends of hydrofluorocarbon (HFC) components R-32 and R-125 from the People's Republic of China (China) are circumventing the antidumping duty (AD) order on HFC blends from China.

DATES: Applicable March 18, 2020.

FOR FURTHER INFORMATION CONTACT: Andrew Medley or Jacob Garten, 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) 482–4987 or (202) 482–3342, respectively.

SUPPLEMENTARY INFORMATION:

Background

On January 27, 2020, Commerce published the *Preliminary Determination* [1] of circumvention of the antidumping duty order on HFC blends from China with respect to blends of R-32 and R-125 which are imported from China and further processed into HFC blends subject to the order.[2] Although we invited parties to comment on the *Preliminary Determination* of this inquiry, we received no comments. Accordingly, no decision memorandum accompanies this **Federal Register** notice.[3] We notified the International Trade Commission (ITC) of our preliminary determination in accordance with section 781(e) of the Act and did not receive a request for consultations from the ITC.[4] Commerce conducted this anti-circumvention inquiry in accordance with section 781(a) of the Tariff Act of 1930, as amended (the Act).

Scope of the Order

The products subject to the *Order* are HFC blends. HFC blends covered by the scope are R-404A, a zeotropic mixture consisting of 52 percent 1,1,1 Trifluoroethane, 44 percent Pentafluoroethane, and 4 percent 1,1,1,2-Tetrafluoroethane; R-407A, a zeotropic mixture of 20 percent Difluoromethane, 40 percent Pentafluoroethane, and 40 percent 1,1,1,2-Tetrafluoroethane; R-407C, a zeotropic mixture of 23 percent Difluoromethane, 25 percent Pentafluoroethane, and 52 percent 1,1,1,2-Tetrafluoroethane; R-410A, a zeotropic mixture of 50 percent Difluoromethane and 50 percent Pentafluoroethane; and R-507A, an azeotropic mixture of 50 percent Pentafluoroethane and 50 percent 1,1,1-Trifluoroethane also known as R-507. The foregoing percentages are nominal percentages by weight. Actual percentages of single component refrigerants by weight may vary by plus or minus two percent points from the nominal percentage identified above.[5]

Any blend that includes an HFC component other than R-32, R-125, R-143a, or R-134a is excluded from the scope of the *Order.*

Excluded from the *Order* are blends of refrigerant chemicals that include products other than HFCs, such as blends including chlorofluorocarbons (CFCs), hydrochlorofluorocarbons (HCFCs), hydrocarbons (HCs), or hydrofluoroolefins (HFOs).

Also excluded from the *Order* are patented HFC blends, including, but not limited to, ISCEON® blends, including MO99™ (R-438A), MO79 (R-422A), MO59 (R-417A), MO49Plus™ (R-437A) and MO29™ (R-4 22D), Genetron® Performax™ LT (R-407F), Choice® R-421A, and Choice® R-421B.

HFC blends covered by the scope of the *Order* are currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) at subheadings 3824.78.0020 and 3824.78.0050. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope is dispositive.[6]

Merchandise Subject to the Anti-Circumvention Inquiry

This anti-circumvention inquiry covers imports of partially finished blends of HFC components R-32 (also known as Difluoromethane) and R-125 (also known as Pentafluoroethane) from China that must be further processed in the United States to create an HFC blend that would be subject to the *Order.*

Final Determination

In the *Preliminary Determination,* we determined that imports of unfinished blends of HFC components R-32 and R-125 from China are circumventing the *Order.* Specifically, we determined that imports of unfinished blends of HFC components R-32 and R-125 from China are being finished and sold in the United States pursuant to the statutory and regulatory criteria laid out in section 781(a) of the Act and 19 CFR 351.225(g). We based our *Preliminary Determination* upon record evidence submitted by the petitioners and U.S. Customs and Border Protection (CBP). For a complete discussion of the evidence which led to our preliminary determination, *see* the *Preliminary Determination.*

Because no party to this inquiry nor the ITC provided any additional information or comments regarding our *Preliminary Determination,* our final determination remains unchanged from the *Preliminary Determination.* Accordingly, we determine, pursuant to section 781(a) of the Act and 19 CFR 351.225(g), that imports of unfinished blends of HFC components R-32 and R-125 from China are circumventing the *Order.*

Continuation of Suspension of Liquidation

As a result of this determination, and consistent with 19 CFR 351.225(l)(3), we intend to direct CBP to continue to suspend liquidation and to require a cash deposit of estimated antidumping duties at the applicable rate on unliquidated entries of merchandise subject to this inquiry that are entered, or withdrawn from warehouse, for consumption on or after June 18, 2019, the date of initiation of this anti-circumvention inquiry.[7]

Notification Regarding Administrative Protective Order

This notice also serves as a reminder to parties subject to the 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 return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

[1] *See Hydrofluorocarbon Blends from the People's Republic of China: Affirmative Preliminary Determination of Circumvention of the Antidumping Duty Order; Unfinished R-32/R-125 Blends,* 85 FR 4632, 4635 (January 27, 2020) (*Preliminary Determination*).

[2] *See Hydrofluorocarbon Blends from the People's Republic of China: Antidumping Duty Order,* 81 FR 55436 (August 19, 2016) (*Order*).

[3] For further details of the issues addressed in this proceeding, *see Preliminary Determination.*

[4] *See* Commerce's Letter, ''Hydrofluorocarbon Blends from the People's Republic of China: Preliminary Determination of Circumvention of the Antidumping Duty Order,'' dated January 23, 2020.

[5] R-404A is sold under various trade names, including Forane® 404A, Genetron® 404A, Solkane® 404A, Klea® 404A, and Suva®404A. R-407A is sold under various trade names, including Forane® 407A, Solkane® 407A, Klea®407A, and Suva®407A. R-407C is sold under various trade names, including Forane® 407C, Genetron® 407C, Solkane® 407C, Klea® 407C and Suva® 407C. R-410A is sold under various trade names, including EcoFluor R410, Forane® 410A, Genetron® R410A and AZ-20, Solkane® 410A, Klea® 410A, Suva® 410A, and Puron®. R-507A is sold under various trade names, including Forane® 507, Solkane® 507, Klea®507, Genetron®AZ-50, and Suva®507. R-32 is sold under various trade names, including Solkane®32, Forane®32, and Klea®32. R-125 is sold under various trade names, including Solkane®125, Klea®125, Genetron®125, and Forane®125. R-143a is sold under various trade names, including Solkane®143a, Genetron®143a, and Forane®125.

[6] *See Order.*

[7] *See Hydrofluorocarbon Blends from the People's Republic of China: Initiation of Anti-Circumvention Inquiry of Antidumping Duty Order; Unfinished Blends,* 84 FR 28276, 28278 (June 18, 2018).

Notification to Interested Parties

We are issuing and publishing this notice in accordance with sections 781(a) and 777(i) of the Act, and 19 CFR 351.213(h) and 351.221(b)(5).

Dated: March 11, 2020.

Christian Marsh,

Deputy Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2020–05609 Filed 3–17–20; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–844]

Steel Concrete Reinforcing Bar From Mexico: Affirmative Preliminary Determination of Circumvention of the Antidumping Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: We preliminarily determine that steel concrete reinforcing bar (rebar) from Mexico that is bent on one or both ends and otherwise meeting the description of in-scope merchandise—if produced and/or exported by Deacero S.A.P.I. de C.V. (Deacero) to the United States—is circumventing the antidumping duty order on rebar from Mexico.

DATES: Applicable March 18, 2020.

FOR FURTHER INFORMATION CONTACT: Jonathan Hall-Eastman, Office III, Antidumping and Countervailing Duty Operations, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1468.

SUPPLEMENTARY INFORMATION:

Background

On September 15, 2014, the Department of Commerce (Commerce) published antidumping duty (AD) *Order* on rebar from Mexico.[1] On October 18, 2019, in response to a request from the Rebar Trade Action Coalition (the petitioner),[2] Commerce initiated a circumvention inquiry into whether imports of otherwise straight rebar bent on one or both ends (also referred to as hooked rebar) that is produced and/or exported to the United States by Deacero and otherwise meeting the description of in-scope merchandise, constitutes merchandise ''altered in form or appearance in minor respects'' from in-scope merchandise that should be considered subject to AD *Order* on rebar from Mexico.[3] Commerce also indicated that it would examine ''whether to apply the results of this anti-circumvention inquiry to imports of similarly situated other straight rebar bent at one or both ends from Mexico regardless of producer or exporter.''[4] For a complete description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[5]

Scope of the Order

The merchandise subject to this *Order* is steel concrete reinforcing bar imported in either straight length or coil form (rebar) regardless of metallurgy, length, diameter, or grade. The subject merchandise is classifiable in the Harmonized Tariff Schedule of the United States (HTSUS) primarily under item numbers 7213.10.0000, 7214.20.0000, and 7228.30.8010.

The subject merchandise may also enter under other HTSUS numbers including 7215.90.1000, 7215.90.5000, 7221.00.0017, 7221.00.0018, 7221.00.0030, 7221.00.0045, 7222.11.0001, 7222.11.0057, 7222.11.0059, 7222.30.0001, 7227.20.0080, 7227.90.6085, 7228.20.1000, and 7228.60.6000. Specifically excluded are plain rounds (*i.e.,* non-deformed or smooth rebar). Also excluded from the scope is deformed steel wire meeting ASTM A1064/A1064M with no bar markings (*e.g.,* mill mark, size or grade) and without being subject to an elongation test. HTSUS numbers are provided for convenience and customs purposes; however, the written description of the scope remains dispositive.

Scope of the Circumvention Inquiry

The merchandise subject to this circumvention inquiry consists of otherwise straight steel concrete reinforcing bar bent on one or both ends and otherwise meeting the description of in-scope merchandise under the *Order* produced and/or exported by Deacero from Mexico to the United States. The petitioner's December 27, 2019 filing stated that:

> the issues present in this anti-circumvention inquiry are limited to deterring circumvention of the order due to modification of straight length with a hook or bend that is easily removable, has no commercially relevant purpose, and is not designed to an industry standard design for incorporation into a specific construction project. Petitioner does not attempt to include all fabricated products in the scope of the order as minor alterations and this issue is not before the Department.[6]

The petitioner's January 31, 2020 filing further noted that ''the issue before the Department is whether Deacero's sales to (a particular customer) circumvented the order.''[7] Unlike for Deacero, we preliminarily find there is no evidence on the record of this inquiry indicating that other Mexican producers are exporting hooked rebar to the United States that did not have a connection to a specific, identified construction project. Therefore, we have not applied our preliminary affirmative finding to hooked rebar country-wide.[8]

Statutory and Regulatory Framework

Section 781(c) of the Tariff Act of 1930, as amended (the Act), which deals with minor alterations of merchandise, states that:

> (1) In general: The class or kind of merchandise subject to (A) an investigation under this title, (B) an antidumping duty order issued under section 736, (C) a finding issued under the Antidumping Act, 1921, or (D) a countervailing duty order issued under section 706 or section 303, shall include articles altered in form or appearance in minor respects (including raw agricultural products that have undergone minor processing), whether or not included in the same tariff classification. (2) Exception. Paragraph (1) shall not apply with respect to altered merchandise if the administering authority determines that it would be unnecessary to consider the altered merchandise within the scope of the investigation, order, or finding.

As stated under 19 CFR 351.225(a), issues may arise as to whether a particular product is included within the scope of an AD or countervailing duty (CVD) order or a suspended investigation. Such issues can arise

[1] *See Steel Concrete Reinforcing Bar from Mexico: Final Determination of Sales at Less Than Fair Value and Final Affirmative Determination of Critical Circumstances,* 79 FR 54967 (September 15, 2014) (*Order*).

[2] *See* Petitioner's Letter, ''Steel Concrete Reinforcing Bar from Mexico: Request for Scope Ruling or, Alternatively, an Anti-Circumvention Ruling,'' dated September 3, 2019.

[3] *See Steel Concrete Reinforcing Bar from Mexico: Initiation of Anti-Circumvention Inquiry of Antidumping Duty Order;* 84 FR 58132 (October 30, 2019), and accompanying Initiation Memorandum.

[4] *Id.,* Initiation Memorandum at 8–9.

[5] *See* Memorandum, ''Affirmative Preliminary Decision Memorandum of Circumvention Concerning Certain Hooked or Bent Steel Concrete Reinforcing Bar Produced and/or Exported by Deacero S.A.P.I. de C.V,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[6] *See* Petitioner's Letter ''*Steel Concrete Reinforcing Bar from Mexico:* Response to Deacero December 10, 2019 Comments,'' dated December 27, 2019, at 2.

[7] *See* Petitioner's Letter, ''*Steel Concrete Reinforcing Bar from Mexico:* Response to Deacero's January 15, 2020 Comments,'' dated January 31, 2020, at 9.

[8] For further information, *see* the Preliminary Decision Memorandum.

because the descriptions of subject merchandise contained in Commerce's determinations must be written in general terms. At other times, a domestic interested party may allege that a change to an imported product or the place where the imported product is assembled constitutes circumvention under section 781 of the Act. When such issues arise, Commerce conducts circumvention inquiries that clarify the scope of an order or suspended investigation with respect to particular products. Pursuant to section 781(c) of the Act and 19 CFR 351.225(i), Commerce may include within the scope of an AD or CVD order articles altered in form or appearance in minor respects.

While the statute is silent regarding what factors to consider in determining whether alterations are properly considered ''minor,'' the legislative history of this provision indicates that there are certain factors which should be considered before reaching a circumvention determination. Previous circumvention cases [9] have relied on the factors listed in the Senate Finance Committee report on the Omnibus Trade and Competitiveness Act of 1988 (which amended the Act to include the circumvention provisions contained in section 781 of the Act), which states:

> {i}n applying this provision, the Commerce Department should apply practical measurements regarding minor alterations, so that circumvention can be dealt with effectively, even where such alterations to an article technically transform it into a differently designated article. The Commerce Department should consider such criteria as the overall physical characteristics of the merchandise, the expectations of the ultimate users, the use of the merchandise, the channels of marketing and the cost of any modification relative to the total value of the imported products.[10]

In the case of an allegation of a ''minor alteration'' under section 781(c) of the Act, it is Commerce's practice to look at the five factors listed in the Senate Finance Committee report to determine if circumvention exists in a particular case.[11]

Preliminary Determination

We preliminarily determine that hooked rebar and straight rebar are not significantly dissimilar in terms of overall physical characteristics of the merchandise, the expectations of the ultimate users, the use of the merchandise, channels of marketing, and the timing and circumstances under which Deacero exported the hooked rebar. We also preliminarily determine that, based on the information submitted by Deacero, there is a significant dissimilarity in production costs between the hooked rebar and straight rebar. Because we find that hooked rebar and straight rebar are not significantly dissimilar as regards the first four criteria, and based on the timing and circumstances under which Deacero exported the hooked rebar, we preliminarily determine that the hooked rebar at issue produced and/or exported by Deacero constitutes merchandise ''altered in form or appearance in minor respects'' from in-scope merchandise, within the meaning of section 781(c)(1) of the Act.[12]

Also, we preliminarily determine there is no evidence on the record of this inquiry indicating that other Mexican producers and exporters of hooked rebar to the United States are circumventing the AD *Order* on rebar from Mexico. Further, unlike *Aluminum Extrusions,*[13] where Commerce applied a circumvention finding country-wide, there are no arguments or information on the record that demonstrates the need for Commerce to extend our preliminary findings to all Mexican producers.[14]

Suspension of Liquidation

In accordance with section 351.225(l)(2) of Commerce's regulations, we will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of otherwise straight steel concrete reinforcing bar bent on one or both ends and otherwise meeting the description of in-scope merchandise under the *Order* that is produced and/or exported to the United States by Deacero that are entered, or withdrawn from warehouse, for consumption on or after October 18, 2019, the date of the initiation of this inquiry. Pursuant to 19 CFR 351.225(l)(2), we will also instruct CBP to require a cash deposit of estimated duties equal to the AD rate in effect for Deacero for each unliquidated entry of otherwise straight steel concrete reinforcing bar bent on one or both ends and otherwise meeting the description of in-scope merchandise under the *Order* that is produced and/or exported to the United States by Deacero on or after October 18, 2019.[15] The suspension of liquidation instructions will remain in effect until further notice.

Hooked rebar produced and/or exported by Deacero that has been sold in connection with a specific, identified construction project and produced according to an engineer's structural design, consistent with industry standards, is not subject to this inquiry. However, imports of such merchandise are subject to certification requirements, and cash deposits may be required if the certification requirements are not satisfied. Accordingly, if an importer imports hooked rebar from Mexico produced and/or exported by Deacero and claims that the hooked rebar has been sold in connection with a specific, identified construction project and produced according to an engineer's structural design, consistent with industry standards, the importer is required to meet the certification and documentation requirements described in Appendices II and III, in order for cash deposits pursuant to the Mexico rebar order not to be required.

Public Comment

Interested parties are invited to comment on this preliminary determination of circumvention and may submit case briefs and/or written comments within 20 days of the publication of this notice.[16] Interested parties may file rebuttal briefs limited to issues raised in the case briefs no later than 10 days after the date on which the case briefs are due.[17] Interested parties may request a hearing within 20 days of the publication of this notice. Interested parties will be notified by Commerce of the location and time of any hearing, if one is requested.

Notification to Interested Parties

This affirmative preliminary circumvention determination is in

[9] *See, e.g., Final Determination of Circumvention of the Antidumping Order: Cut-to-Length Carbon Steel Plate From Canada,* 66 FR 7617, 7618 (January 24, 2001)) (*CTL Plate from Canada*), and accompanying Issues and Decision Memorandum (IDM) at Comment 4, in which Commerce discusses its application of the factors discussed in the Senate Finance Committee report; *see also Final Results of Anti-Circumvention Review of Antidumping Order: Corrosion-Resistant Carbon Steel Flat Products From Japan,* 68 FR 33676, 33677 (June 5, 2003); and *Affirmative Final Determination of Circumvention of the Antidumping Duty Order on Certain Cut-to-Length Carbon Steel Plate From the People's Republic of China,* 74 FR 40565, 40566 (August 12, 2009), and accompanying IDM.

[10] *See* Omnibus Trade Act of 1987, Report of the Senate Finance Committee, S. Rep. No. 71, 100th Cong., 1st Sess. 100 (1987).

[11] *See, e.g., CTL Plate from Canada* IDM at Comment 4.

[12] For additional information, *see* the Preliminary Decision Memorandum.

[13] *See Aluminum Extrusions from the People's Republic of China: Final Affirmative Determination of Circumvention of the Antidumping Duty and Countervailing Duty Orders, and Partial Rescission,* 84 FR 39805 (August 12, 2019) (*Aluminum Extrusions*), and accompanying IDM at 18.

[14] For additional information, *see* the Preliminary Decision Memorandum.

[15] *See Steel Concrete Reinforcing Bar from Mexico: Final Results of Antidumping Duty Administrative Review; 2016–2017,* 84 FR 35599 (July 24, 2019).

[16] *See* 19 CFR 351.225(f)(3).

[17] *Id.*

accordance with section 781(c) of the Act and 19 CFR 351.225.

Dated: February 28, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. Statutory and Regulatory Framework
V. Analysis
A. Whether the Hooked Rebar at Issue Constitutes Merchandise Altered in Form or Appearance in Minor Respects
B. Certification Language
VI. Recommendation

Appendix II

Certification Requirements

If an importer imports otherwise straight rebar bent on one or both ends (hooked rebar) from Mexico produced and/or exported by Deacero and claims that the hooked rebar has been sold in connection with specific, identified construction project and produced according to an engineer's structural design, consistent with industry standards, the importer is required to complete and maintain the importer certification attached hereto as Appendix III and all supporting documentation. Where the importer uses a broker to facilitate the entry process, the importer should obtain the entry number from the broker. Agents of the importer, such as brokers, however, are not permitted to make this certification on behalf of the importer.

For shipments and/or entries from October 18, 2019 through March 29, 2020, if a certification is required, importers should complete the required certification within 30 days of the publication of this notice in the **Federal Register**. Accordingly, where appropriate, the relevant bullet in the certification should be edited to reflect that the certification was completed within the time frame specified above. For example, the bullet in the importer certification that reads: ''This certification was completed at or prior to the time of entry,'' could be edited as follows: ''The imports referenced herein entered before March 30, 2020. This certification was completed on mm/dd/yyyy, within 30 days of the **Federal Register** notice publication of the preliminary determination of circumvention.'' For such entries/shipments, importers have the option to complete a blanket certification covering multiple entries/shipments, individual certifications for each entry/shipment, or a combination thereof.

For shipments and/or entries on or after March 30, 2020, if a certification is required, importers should complete the certification at or prior to the date of entry.

The importer is also required to maintain sufficient documentation supporting its certifications. The importer will not be required to submit the certifications or supporting documentation to U.S. Customs and Border Protection (CBP) as part of the entry process at this time. However, the importer will be required to present the certifications and supporting documentation to Commerce and/or CBP, as applicable, upon request by the respective agency. Additionally, the claims made in the certifications and any supporting documentation are subject to verification by Commerce and/or CBP. The importer is required to maintain the certification and supporting documentation for the later of: (1) A period of five years from the date of entry, or (2) a period of three years after the conclusion of any litigation in United States courts regarding such entries.

In the situation where no certification is provided for an entry, Commerce intends to instruct CBP to suspend liquidation of the entry and collect cash deposits at the rate applicable to Deacero.

Appendix III

Importer Certification

I hereby certify that:

- My name is {IMPORTING COMPANY OFFICIAL'S NAME} and I am an official of {IMPORTING COMPANY};
- I have direct personal knowledge of the facts regarding the importation into the Customs territory of the United States of the otherwise straight rebar bent on one or both ends (hooked rebar) from Mexico produced and/or exported by Deacero S.A.P.I. (Deacero) that entered under entry number(s), identified below, and which are covered by this certification. ''Direct personal knowledge'' for purposes of this certification refers to facts in records maintained by the importing company in the normal course of its business.
- The hooked rebar covered by this certification was produced and/or exported by Deacero.

If the importer is acting on behalf of the first U.S. customer, complete this paragraph:

- The hooked rebar from Mexico produced and/or exported by Deacero covered by this certification was imported by {NAME OF IMPORTING COMPANY} on behalf of {NAME OF U.S. CUSTOMER}, located at {ADDRESS OF U.S. CUSTOMER}.
- The hooked rebar from Mexico produced and/or exported by Deacero covered by this certification was shipped to {NAME OF PARTY TO WHOM MERCHANDISE WAS FIRST SHIPPED IN THE UNITED STATES}, located at {ADDRESS OF SHIPMENT}.
- I have personal knowledge of the facts regarding the production of hooked rebar from Mexico produced and/or exported by Deacero identified below. ''Personal knowledge'' includes facts obtained from another party (*e.g.,* correspondence received by the importer from the producer regarding the country of manufacture of the imported products).
- The hooked rebar from Mexico was produced and/or exported by Deacero.
- The imports of hooked rebar have been sold in connection with a specific, identified construction project and produced according to an engineer's structural design, consistent with industry standards.
- This certification applies to the following entries:

Producer	Entry summary No.	Entry summary line item No.	Invoice No.	Invoice line item No.

- I understand that {NAME OF IMPORTING COMPANY} is required to maintain a copy of this certification and sufficient documentation supporting this certification (*i.e.,* documents maintained in the normal course of business, or documents obtained by the certifying party, for example, mill certificates, production records, invoices, *etc.*) for the later of (1) a period of five years from the date of entry or (2) a period of three years after the conclusion of any litigation in the United States courts regarding such entries.
- I understand that {NAME OF IMPORTING COMPANY} is required to provide this certification and supporting records, upon request, to U.S. Customs and Border Protection (CBP) and/or the Department of Commerce (Commerce).
- I understand that the claims made herein, and the substantiating documentation, are subject to verification by CBP and/or Commerce.
- I understand that failure to maintain the required certifications, and/or failure to substantiate the claims made herein, and/or failure to allow CBP and/or Commerce to verify the claims made herein, may result in a determination that all entries to which this certification applies are within the scope of the antidumping duty order on steel concrete reinforcing bar from Mexico. I understand that such finding could result in:

○ Suspension of liquidation of all unliquidated entries (and entries for which liquidation has not become final) for which these requirements were not met;

○ the requirement that the importer post applicable antidumping duty cash deposits (as appropriate) equal to the rates determined by Commerce; and

○ the revocation of {NAME OF IMPORTING COMPANY}'s privilege to certify future imports of steel concrete reinforcing bar from Mexico.

• I understand that agents of the importer, such as brokers, are not permitted to make this certification.

• This certification was completed at or prior to the time of entry.

• I am aware that U.S. law (including, but not limited to, 18 U.S.C. 1001) imposes criminal sanctions on individuals who knowingly and willfully make materially false statements to the U.S. government.

Signature
NAME OF COMPANY OFFICIAL
TITLE
DATE

[FR Doc. 2020–05608 Filed 3–17–20; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–118]

Wood Mouldings and Millwork Products From the People's Republic of China: Postponement of Preliminary Determination in the Countervailing Duty Investigation

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: Applicable March 18, 2020.

FOR FURTHER INFORMATION CONTACT: Irene Gorelik or Faris Montgomery, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–6905 or (202) 482–1537, respectively.

SUPPLEMENTARY INFORMATION:

Background

On January 28, 2020, the Department of Commerce (Commerce) initiated a countervailing duty (CVD) investigation of imports of wood mouldings and millwork products (millwork products) from the People's Republic of China.[1] Currently, the preliminary determination is due no later than April 2, 2020.

Postponement of Preliminary Determination

Section 703(b)(1) of the Tariff Act of 1930, as amended (the Act), requires the Department to issue the preliminary determination in a countervailing duty investigation within 65 days after the date on which Commerce initiated the investigation. However, section 703(c)(1) of the Act permits Commerce to postpone the preliminary determination until no later than 130 days after the date on which Commerce initiated the investigation if: (A) The petitioner makes a timely request for a postponement; or (B) Commerce concludes that the parties concerned are cooperating, that the investigation is extraordinarily complicated, and that additional time is necessary to make a preliminary determination. Under 19 CFR 351.205(e), the petitioner must submit a request for postponement 25 days or more before the scheduled date of the preliminary determination and must state the reasons for the request. Commerce will grant the request unless it finds compelling reasons to deny the request.

On March 6, 2020, the petitioner[2] submitted a timely request that Commerce postpone the preliminary CVD determination.[3] The petitioner stated that it requests postponement ''because additional time will be necessary to receive questionnaire responses and to ensure that the Department {of Commerce} has sufficient time to review all responses and request clarification and additional information as necessary.''[4]

In accordance with 19 CFR 351.205(e), the petitioner has stated the reasons for requesting a postponement of the preliminary determination, and Commerce finds no compelling reason to deny the request. Therefore, in accordance with section 703(c)(1)(A) of the Act, Commerce is postponing the deadline for the preliminary determination to no later than 130 days after the date on which this investigation was initiated, *i.e.,* June, 8, 2020.[5] Pursuant to section 705(a)(1) of the Act and 19 CFR 351.210(b)(1), the deadline for the final determination of this investigation will continue to be 75 days after the date of the preliminary determination.

Notification to Interested Parties

This notice is issued and published pursuant to section 703(c)(2) of the Act and 19 CFR 351.205(f)(1).

Dated: March 12, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2020–05610 Filed 3–17–20; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See Wood Mouldings and Millwork Products from the People's Republic of China: Initiation of Countervailing Duty Investigation,* 85 FR 6513 (February 5, 2020) (*Initiation Notice*).

[2] The petitioner is the Coalition of American Millwork Producers.

[3] *See* Petitioner's Letter, ''Wood Mouldings and Millwork Products from the People's Republic of China: Request to Postpone Preliminary Determination,'' dated March 6, 2020.

[4] *Id.*

[5] Postponing the preliminary determination to 130 days after initiation would place the deadline on Saturday, June 6, 2020. Commerce's practice dictates that where a deadline falls on a weekend or federal holiday, the appropriate deadline is the next business day. *See Notice of Clarification: Application of ''Next Business Day'' Rule for Administrative Determination Deadlines Pursuant to the Tariff Act of 1930, As Amended,* 70 FR 24533 (May 10, 2005).

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA087]

Pacific Fishery Management Council; Public Meetings

AGENCY: National Marine Fisheries Service, National Oceanic and Atmospheric Administration, Commerce.

ACTION: Notice of public meetings.

SUMMARY: The Pacific Fishery Management Council (Pacific Council) and its advisory entities will hold public meetings.

DATES: The Pacific Council and its advisory entities will meet April 4–10, 2020. The Pacific Council meeting will begin on Sunday, April 5, 2020 at 8 a.m. Pacific Daylight Time (PDT), reconvening at 8 a.m. each day through Friday, April 10, 2020. All meetings are open to the public, except a closed session will be held from 8 a.m. to 9 a.m., Sunday, April 5, to address litigation and personnel matters. The Pacific Council will meet as late as necessary each day to complete its scheduled business.

ADDRESSES: Meetings of the Pacific Council and its advisory entities will be held at the Hilton Vancouver, 301 West 6th Street, Vancouver, WA; telephone: (360) 993–4500.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220. Instructions for attending the meeting via live stream broadcast are given under **SUPPLEMENTARY INFORMATION**, below.

FOR FURTHER INFORMATION CONTACT: Mr. Chuck Tracy, Executive Director; telephone: (503) 820–2280 or (866) 806–7204 toll-free; or access the Pacific Council website, *http://www.pcouncil.org* for the current meeting location, proposed agenda, and meeting briefing materials.

SUPPLEMENTARY INFORMATION: The April 5–10, 2020 meeting of the Pacific Council will be streamed live on the internet. The broadcasts begin initially at 9 a.m. PDT Sunday, April 5, 2020 and continue at 8 a.m. daily through Friday, April 10, 2020. Broadcasts end when

business for the day is complete. Only the audio portion and presentations displayed on the screen at the Pacific Council meeting will be broadcast. The audio portion is listen-only; you will be unable to speak to the Pacific Council via the broadcast. You can attend the webinar online using a computer, tablet, or smart phone, using the RingCentral application. To access the meeting online, please use the following link: *https://webinar.ringcentral.com/j/1482157036,* or if you already have RingCentral Meeting installed you may join the meeting using the ID: 148–215–7036. It is recommended that you use a computer headset to listen to the meeting, but you may use your telephone for the audio-only portion of the meeting. The audio portion may be attended using a telephone by following the connect to audio instructions on your screen, shown after joining the webinar.

Please note that the evolving public health situation regarding COVID–19 may affect the conduct of the April Council meeting. At the time this notice was submitted for publication, we anticipated the April meetings of the Pacific Council and its Advisory Bodies would be conducted as planned, in person, and without opportunities for remote participation other than the broadcast noted above. Pacific Council staff will monitor COVID–19 developments and will determine if there is a need to allow some additional level of remote participation or other contingency plan such as postponement of non-essential agenda items. If such measures are deemed necessary, Council staff will post notice of them prominently on our website (*www.pcouncil.org*). Potential meeting participants are encouraged to check the Pacific Council's website frequently for such information and updates.

The following items are on the Pacific Council agenda, but not necessarily in this order. Agenda items noted as ''Final Action'' refer to actions requiring the Council to transmit a proposed fishery management plan, proposed plan amendment, or proposed regulations to the U.S. Secretary of Commerce, under Sections 304 or 305 of the Magnuson-Stevens Fishery Conservation and Management Act. Additional detail on agenda items, Council action, advisory entity meeting times, and meeting rooms are described in Agenda Item A.4, Proposed Council Meeting Agenda, and will be in the advance April 2020 briefing materials and posted on the Pacific Council website at *www.pcouncil.org* no later than Friday, March 20, 2020.

A. Call to Order

1. Opening Remarks
2. Roll Call
3. Executive Director's Report
4. Approve Agenda

B. Open Comment Period

1. Comments on Non-Agenda Items

C. Habitat Issues

1. Current Habitat Issues

D. Coastal Pelagic Species Management

1. National Marine Fisheries Service Report
2. Exempted Fishing Permits (EFPs) for 2020–21—Final Action
3. Pacific Sardine Assessment, Harvest Specifications, and Management Measures—Final Action
4. Essential Fish Habitat Review—Scoping
5. Preliminary Pacific Sardine Rebuilding Plan

E. Salmon Management

1. Tentative Adoption of 2020 Management Measures for Analysis
2. Essential Fish Habitat for Stocks Declared Overfished
3. Southern Oregon/Northern California Coast Coho Endangered Species Act Consultation Process
4. Clarify Council Direction on 2020 Management Measures
5. Methodology Review Preliminary Topic Selection
6. Salmon Reintroduction Above Grand Coulee Dam
7. Further Direction on 2020 Management Measures
8. Amendment 20: Annual Management Cycle and Management Boundary Change
9. 2020 Management Measures—Final Action

F. Enforcement

1. Annual U.S. Coast Guard Fishery Enforcement Report

G. Groundfish Management

1. National Marine Fisheries Service Report
2. Cost Recovery Report and Preliminary Regulation Changes
3. Implementation of the 2020 Pacific Whiting Fishery Under the U.S./Canada Agreement
4. Biennial Harvest Specifications for 2021–22 Fisheries—Final Action
5. Electronic Monitoring Program Review
6. Preliminary Preferred Management Measure Alternatives for 2021–22 Fisheries
7. Workload and New Management Measures Prioritization
8. Inseason Adjustments—Final Action

H. Pacific Halibut Management

1. Incidental Catch Limits for 2020 Salmon Troll Fishery—Final Action

I. Administrative Matters

1. Legislative Matters
2. Fiscal Matters
3. Membership Appointments; Statement of Organization, Practices, and Procedures; and Council Operating Procedures
4. Future Council Meeting Agenda and Workload Planning

Advisory Body Agendas

Advisory body agendas will include discussions of relevant issues that are on the Pacific Council agenda for this meeting and may also include issues that may be relevant to future Council meetings. Proposed advisory body agendas for this meeting will be available on the Pacific Council website *http://www.pcouncil.org/council-operations/council-meetings/current-briefing-book/* no later than Friday, March 20, 2020.

Schedule of Ancillary Meetings

Day 1—Saturday, April 4, 2020

Coastal Pelagic Species Advisory Subpanel 8 a.m.
Coastal Pelagic Species Management Team 8 a.m.
Groundfish Electronic Monitoring Policy Advisory Committee and Technical Advisory Committee 8 a.m.
Habitat Committee 8 a.m.
Salmon Advisory Subpanel 8 a.m.
Salmon Technical Team 8 a.m.
Scientific and Statistical Committee 8 a.m.
Legislative Committee 10 a.m.
Model Evaluation Workgroup 10 a.m.
Budget Committee 1 p.m.
Tribal Policy Group As Necessary
Tribal and Washington Technical Group As Necessary

Day 2—Sunday, April 5, 2020

California State Delegation 7 a.m.
Oregon State Delegation 7 a.m.
Washington State Delegation 7 a.m.
Coastal Pelagic Species Advisory Subpanel 8 a.m.
Coastal Pelagic Species Management Team 8 a.m.
Enforcement Consultants 8 a.m.
Groundfish Advisory Subpanel 8 a.m.
Groundfish Management Team 8 a.m.
Salmon Advisory Subpanel 8 a.m.
Salmon Technical Team 8 a.m.
Scientific and Statistical Committee 8 a.m.
Tribal Policy Group As Necessary
Tribal and Washington Technical Group As Necessary

Day 3—Monday, April 6, 2020

California State Delegation 7 a.m.
Oregon State Delegation 7 a.m.
Washington State Delegation 7 a.m.
Groundfish Advisory Subpanel 8 a.m.
Groundfish Management Team 8 a.m.
Salmon Advisory Subpanel 8 a.m.
Salmon Technical Team 8 a.m.
Enforcement Consultants As Necessary
Tribal Policy Group As Necessary
Tribal and Washington Technical Group As Necessary

Day 4—Tuesday, April 7, 2020

California State Delegation 7 a.m.
Oregon State Delegation 7 a.m.
Washington State Delegation 7 a.m.
Groundfish Advisory Subpanel 8 a.m.
Groundfish Management Team 8 a.m.
Salmon Advisory Subpanel 8 a.m.
Salmon Technical Team 8 a.m.
Enforcement Consultants As Necessary
Tribal Policy Group As Necessary
Tribal and Washington Technical Group As Necessary

Day 5—Wednesday, April 8, 2020

California State Delegation 7 a.m.
Oregon State Delegation 7 a.m.
Washington State Delegation 7 a.m.
Groundfish Advisory Subpanel 8 a.m.
Groundfish Management Team 8 a.m.
Salmon Advisory Subpanel 8 a.m.
Salmon Technical Team 8 a.m.
Enforcement Consultants As Necessary
Tribal Policy Group As Necessary
Tribal and Washington Technical Group As Necessary

Day 6—Thursday, April 9, 2020

California State Delegation 7 a.m.
Oregon State Delegation 7 a.m.
Washington State Delegation 7 a.m.
Groundfish Advisory Subpanel 8 a.m.
Groundfish Management Team 8 a.m.
Salmon Advisory Subpanel 8 a.m.
Salmon Technical Team 8 a.m.
Enforcement Consultants As Necessary
Tribal Policy Group As Necessary
Tribal and Washington Technical Group As Necessary

Day 7—Friday, April 10, 2020

California State Delegation 7 a.m.
Oregon State Delegation 7 a.m.
Washington State Delegation 7 a.m.
Salmon Technical Team 8 a.m.

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

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt at (503) 820–2412 at least 10 business days prior to the meeting date.

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

Dated: March 13, 2020.

Tracey L. Thompson,

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

[FR Doc. 2020–05618 Filed 3–17–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA085]

Mid-Atlantic Fishery Management Council (MAFMC); Public Meeting

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

ACTION: Notice; public meetings.

SUMMARY: The Atlantic Mackerel, Squid, and Butterfish (MSB) Advisory Panel of the Mid-Atlantic Fishery Management Council (Council) will hold two meetings.

DATES: The meetings will be held on Tuesday, March 31, 2020 and Tuesday, April 14, 2020. Both will begin at 3 p.m. and conclude by 6 p.m. For agenda details, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: The meetings will be held via webinar with a telephone-only audio connection: *http://mafmc.adobeconnect.com/illex-wg/.* Telephone instructions are provided upon connecting, or the public can call direct: (800) 832–0736, Rm: *7833942#.

Council address: Mid-Atlantic Fishery Management Council, 800 N State Street, Suite 201, Dover, DE 19901; telephone: (302) 674–2331 or on their website at *www.mafmc.org.*

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, telephone: (302) 526–5255.

SUPPLEMENTARY INFORMATION: The primary purpose of the meetings is to gather Advisory Panel input on analysis related to possible changes to the *Illex* squid quota. An agenda and any background documents will be posted at the Council's website (*www.mafmc.org*) prior to the meeting. At the March 31, 2020 meeting, the Advisory Panel will be asked for input on creating a Fishery Performance Report for the *Illex* fishery.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to M. Jan Saunders, (302) 526–5251, at least 5 days prior to any meeting date.

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

Dated: March 13, 2020.

Tracey L. Thompson,

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

[FR Doc. 2020–05621 Filed 3–17–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Telecommunications and Information Administration

Multistakeholder Process on Promoting Software Component Transparency

AGENCY: National Telecommunications and Information Administration, U.S. Department of Commerce.

ACTION: Notice of open meeting.

SUMMARY: The National Telecommunications and Information Administration (NTIA) will convene a virtual meeting of a multistakeholder process on promoting software component transparency on April 15, 2020.

DATES: The meeting will be held on April 15, 2020, from 10:00 a.m. to 4:00 p.m., Eastern Time.

ADDRESSES: The meeting will be held virtually, with online slide share and dial-in information to be posted at *https://www.ntia.doc.gov/SoftwareTransparency.*

FOR FURTHER INFORMATION CONTACT: Allan Friedman, National Telecommunications and Information Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Room 4725, Washington, DC 20230; telephone: (202) 482–4281; email: *afriedman@ntia.doc.gov.* Please direct media inquiries to NTIA's Office of Public Affairs: (202) 482–7002; email: *press@ntia.doc.gov.*

SUPPLEMENTARY INFORMATION:

Background

This National Telecommunications and Information Administration cybersecurity multistakeholder process focuses on promoting software component transparency. Most modern software is not written completely from scratch, but includes existing components, modules, and libraries from the open source and commercial software world. Modern development practices such as code reuse, and a dynamic IT marketplace with acquisitions and mergers, make it challenging to track the use of software components. The Internet of Things compounds this phenomenon, as new organizations, enterprises, and innovators take on the role of software developer to add ''smart'' features or connectivity to their products. While the majority of libraries and components do not have known vulnerabilities, many do, and the sheer quantity of software means that some software products ship with vulnerable or out-of-date components.

The first meeting of this multistakeholder process was held on July 19, 2018, in Washington, DC.[1] Stakeholders presented multiple perspectives, and identified several inter-related work streams: Understanding the Problem, Use Cases and State of Practice, Standards and Formats, and Healthcare Proof of Concept. Since then, stakeholders have been discussing key issues and developing products such as guidance documents. NTIA acts as the convener, but stakeholders drive the outcomes. Success of the process will be evaluated by the extent to which broader findings on software component transparency are implemented across the ecosystem.

The first set of stakeholder-drafted documents on Software Bills of Materials was published by NTIA in November 2019. Those documents, and subsequent consensus-approved drafts from the community are published at: *https://www.ntia.doc.gov/SBOM.* The main objectives of the April 15, 2020, meeting are to share progress from the working groups; to give feedback on the ongoing work around technical challenges, tooling, demonstrations, and awareness and adoption; and to begin discussions around potential guidance or playbook documents. More information about stakeholders' work is available at: *https://www.ntia.doc.gov/SoftwareTransparency.*

Time and Date: NTIA will convene the next meeting of the multistakeholder process on Software Component Transparency on April 15, 2020, from 10:00 a.m. to 4:00 p.m. Eastern Time. The exact time of the meeting is subject to change. Please refer to NTIA's website, *https://www.ntia.doc.gov/SoftwareTransparency,* for the most current information.

Place: The meeting will be held virtually, with online slide share and dial-in information to be posted at *https://www.ntia.doc.gov/SoftwareTransparency.* Please refer to NTIA's website, *https://www.ntia.doc.gov/SoftwareTransparency*, for the most current information.

Other Information: The meeting is open to the public and the press on a first-come, first-served basis.

The virtual meeting is accessible to people with disabilities. Requests for real-time captioning or other auxiliary aids should be directed to Allan Friedman at (202) 482–4281 or *afriedman@ntia.doc.gov* at least seven (7) business days prior to the meeting. Access details for the meeting are subject to change. Please refer to NTIA's website, *https://www.ntia.doc.gov/SoftwareTransparency*, for the most current information.

Dated: March 13, 2020.

Kathy D. Smith,

Chief Counsel, National Telecommunications and Information Administration.

[FR Doc. 2020–05666 Filed 3–17–20; 8:45 am]

BILLING CODE 3510–60–P

[1] Notes, presentations, and a video recording of the July 19, 2018, kickoff meeting are available at: *https://www.ntia.doc.gov/SoftwareTransparency.*

COMMODITY FUTURES TRADING COMMISSION

Agency Information Collection Activities: Notice of Intent To Extend Collection Number 3038–0049: Procedural Requirements for Requests for Interpretative, No-Action, and Exemptive Letters

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice.

SUMMARY: The Commodity Futures Trading Commission (''Commission'' or ''CFTC'') is announcing an opportunity for public comment on the proposed extension of a collection of certain information by the agency. Under the Paperwork Reduction Act (''PRA''), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment. This notice solicits comments on requirements related to requests for, and the issuance of, exemptive, no-action, and interpretative letters.

DATES: Comments must be submitted on or before May 18, 2020.

ADDRESSES: You may submit comments, identified by ''OMB Control Number 3038–0049,'' by any of the following methods:

- The CFTC website, at *https://comments.cftc.gov/.* Follow the instructions for submitting comments through the website.
- *Mail:* Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.
- *Hand Delivery/Courier:* Same as Mail above.

Please submit your comments using only one method. All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *https://www.cftc.gov.*

FOR FURTHER INFORMATION CONTACT: Jacob Chachkin, Special Counsel, Division of Swap Dealer and Intermediary Oversight, (202) 418–5496, email: *jchachkin@cftc.gov;* Steven Haidar, Special Counsel, Division of Market Oversight, (202) 418–5611, email: *shaidar@cftc.gov;* or Melissa D'Arcy, Special Counsel, Division of Clearing and Risk, (202) 418–5086, email: *mdarcy@cftc.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA, 44 U.S.C. 3501 *et seq.,* Federal agencies must obtain approval from the Office of Management and Budget (''OMB'') for each collection of information they conduct or sponsor. ''Collection of Information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3 and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA, 44 U.S.C. 3506(c)(2)(A), requires a Federal agency to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information before submitting the collection to OMB for approval. 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 number. To comply with these requirements, the CFTC is publishing notice of the proposed extension of the currently approved collection of information listed below.

Title: Procedural Requirements for Requests for Interpretative, No-Action, and Exemptive Letters (OMB Control No. 3038–0049). This is a request for an extension of a currently approved information collection.

Abstract: This collection covers the information requirements for voluntary requests for, and the issuance of, interpretative, no-action, and exemptive letters submitted to Commission staff pursuant to the provisions of section 140.99 of the Commission's regulations,[1] and related requests for confidential treatment pursuant to section 140.98(b)[2] of the Commission's regulations.

The collection requirements described herein are voluntary. They apply to parties that choose to request a benefit from Commission staff in the form of the regulatory action described in section 140.99. Such benefits may include, for example, relief from some or all of the burdens associated with other collections of information, relief from regulatory obligations that do not constitute collections of information, interpretations, or extensions of time for compliance with certain Commission regulations. It is likely that persons who would opt to request action under section 140.99 will have determined that the information collection burdens that they would assume by doing so will be outweighed substantially by the relief that they seek to receive.

This information collection is necessary, and would be used, to assist Commission staff in understanding the type of relief that is being requested and the basis for the request. It is also necessary, and would be used, to provide staff with a sufficient basis for determining whether: (1) Granting the relief would be necessary or appropriate under the facts and circumstances presented by the requestor; (2) the relief provided should be conditional and/or time-limited; and (3) granting the relief would be consistent with staff responses to requests that have been presented under similar facts and circumstances. In some cases, the requested relief might be granted upon the condition that those who seek the benefits of that relief fulfill certain conditions that are necessary to ensure that the relief granted by Commission staff is appropriate. Once again, it is likely that those who would comply with these conditions will have determined that the burden of complying with the conditions is outweighed by the relief that they seek to receive. This information collection also is necessary to provide a mechanism whereby persons requesting interpretative, no-action, and exemptive letters may seek temporary confidential treatment of their request and the Commission staff response thereto and the grounds upon which such confidential treatment is sought.

With respect to the collection of information, the CFTC invites comments on:

- Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have a practical use;
- The accuracy of the Commission's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Ways to enhance the quality, usefulness, and clarity of the information to be collected; and
- Ways to minimize the burden of 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.

You should submit only information that you wish to make available publicly. If you wish the Commission to consider information that you believe is exempt from disclosure under the Freedom of Information Act, a petition for confidential treatment of the exempt information may be submitted according to the procedures established in section 145.9 of the Commission's regulations.[3]

The Commission reserves the right, but shall have no obligation to, review, pre-screen, filter, redact, refuse or remove any or all of your submission from *https://www.cftc.gov* that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the Information Collection Requirement will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other applicable laws, and may be accessible under the Freedom of Information Act.

Burden Statement: The Commission is revising its burden estimate for this information collection. The Commission has based its estimate of the annual number of respondents related to this information collection, in part, on the average number of interpretative, no-action, and exemptive letters issued by Commission staff in 2017, 2018, and 2019. The Commission generally estimates that each request was made by a unique respondent. To that number, the Commission is adding additional respondents that have incurred burden hours preparing requests for relief that did not generate a Commission staff letter in response.

This estimate includes the burden hours for preparing, filing, and updating such request letters as well as the burden of complying with any conditions that may be contained in any interpretative, no-action, or exemptive letters granting relief. It also includes burden hours required to prepare and submit related requests for confidential treatment. The burden hours associated with individual requests will vary widely, depending upon the type and complexity of relief requested, whether the request presents novel or complex issues, the relevant facts and circumstances, and the number of requestors or other affected entities.

The respondent burden is estimated to be as follows:

Estimated Number of Annual Respondents: 68.

Estimated Average Annual Burden Hours per Respondent: 40.

Estimated Total Annual Burden Hours: 2,720.

Frequency of Collection: Occasional.

Type of Respondents: Respondents include persons registered with the Commission (such as commodity pool operators, commodity trading advisors, derivatives clearing organizations, designated contract markets, futures commission merchants, introducing brokers, swap dealers, and swap execution facilities), persons seeking an exemption from registration, persons whose registration with the Commission is pending, trade associations and their members, eligible contract participants, and other persons seeking relief from discrete regulatory requirements.

There are no capital costs or operating and maintenance costs associated with this collection.

(Authority 44 U.S.C. 3501 *et seq.*)

Dated: March 12, 2020.

Robert Sidman,

Deputy Secretary of the Commission.

[FR Doc. 2020–05575 Filed 3–17–20; 8:45 am]

BILLING CODE 6351–01–P

[1] 17 CFR 140.99. An archive containing CFTC staff letters may be found at *http://www.cftc.gov/LawRegulation/CFTCStaffLetters/index.htm.*

[2] 17 CFR 140.98(b).

[3] 17 CFR 145.9.

DEPARTMENT OF DEFENSE

Department of the Air Force

Notice of Intent To Prepare a Legislative Environmental Impact Statement and Notice of Scoping Meetings for the Proposed Extension of the Military Land Withdrawal at Barry M. Goldwater Range, Arizona

AGENCY: Department of the Air Force and United States Marine Corps, DoD.

ACTION: Notice of intent.

SUMMARY: The United States Air Force (USAF) (co-lead agency), in coordination with the United States Marine Corps (USMC) (co-lead agency), is issuing this notice to advise the public of the intent to prepare a Legislative Environmental Impact Statement (LEIS) for the proposed extension of the Barry M. Goldwater Range (BMGR) land withdrawal and reservation in Arizona. The LEIS will also address a proposal to withdrawal approximately 2,366 acres of additional public land adjacent to Gila Bend Air Force Auxiliary Airfield to enhance the security and safety of flight operations at the airfield. Five public scoping meetings will be held, which is an important part of the LEIS process as it allows for an early and open process, giving the public an opportunity to help determine the scope of issues and alternatives to be addressed in the LEIS.

DATES: The scoping meetings will be held from 5:30 p.m. to 8:30 p.m., at the locations and dates listed below:

- Thursday, April 9, 2020: Palmcroft Elementary Cafeteria, 901 W Palmcroft Drive, Yuma, AZ 85364
- Monday, April 13, 2020: Longview Elementary, Cafeteria, 1209 E Indian School Rd., Phoenix, AZ 85014
- Tuesday, April 14: Gila Bend Unified Schools Media Center, 308 N Martin Ave., Gila Bend, AZ 85337
- Thursday, April 16, 2020: Ajo Ambulance, Training Room, 1850 N Gila Bend Hwy., Ajo, AZ 85321
- Thursday, April 30, 2020: Flowing Wells Public Library, Multipurpose Room, 1730 W Wetmore Rd., Tucson, AZ 85705

ADDRESSES: Information on the BMGR Land Withdrawal and the LEIS process can be accessed at the project website at *www.barry-m-goldwater-leis.com*. The project website can also be used to submit comments. Inquiries and comments regarding the USAF/USMC proposal may be submitted by mail to BMGR Land Withdrawal LEIS, P.O. Box 2324, Phoenix, AZ 85003, or email to *BMGR_LEIS@jacobs.com*.

To ensure the Air Force and Marine Corps have sufficient time to consider public input in the preparation of the Draft LEIS, scoping comments must be submitted to the website or mailed to one of the addresses listed above no later than May 19, 2020.

FOR FURTHER INFORMATION CONTACT: Mr. Jon Haliscak at 210–395–0615.

SUPPLEMENTARY INFORMATION: The current BMGR land withdrawal and reservation expires in October 2024. In accordance with the Military Lands Withdrawal Act of 1999, the USAF and USMC have notified Congress of a continuing military need for the BMGR. National defense land withdrawal applications have been prepared and submitted to the Bureau of Land Management (BLM) in accordance with the Federal Land Policy and Management Act of 1976.

The purpose of extending the BMGR land withdrawal and reservation is to retain one of the nation's premier ranges for training tactical air-combat aircrews and other military personnel to fight, survive, and win in the air-ground battlespace. The readiness of air and ground forces is dependent on the quantity and quality of tactics development/testing and training that warfighters receive, which, in turn, is reliant on the capacities and capabilities of the ranges available to support their training. The BMGR's attributes of favorable location and flying weather, suitable land and airspace, diverse terrain, and developed training support facilities make it one of the most capable and productive tactical aviation ranges available to U.S. forces, and critical to supporting essential training both now and into the foreseeable future.

The LEIS will analyze various alternatives for extending authorization for the BMGR. Preliminary alternatives have been developed. As part of scoping, comments received during may result in changes or additions to these alternatives.

Alternative 1 would reauthorize the existing land withdrawal and management of BMGR for another 25 years. The USAF and USMC would continue to manage the withdrawn public lands in BMGR East and BMGR West, respectively. The USAF and USMC, through the Offices of the Secretary of the Air Force (SECAF) and Secretary of the Navy (SECNAV), would continue to consult with the Secretary of the Department of the Interior (SECDOI) before using the BMGR for non-reserved purposes. The existing boundary and land area of the BMGR, which encompasses approximately 1,733,921 acres, would not change. Alternative 1A would implement Alternative 1 except the period of withdrawal would be for another 50 years. Alternative 1B would implement Alternative 1 except the withdrawal would be for an indefinite period until the BMGR is no longer needed by the USAF and USMC. Alternative 1C would permanently transfer administrative jurisdiction of the lands comprising BMGR East and BMGR West to SECAF and SECNAV, respectively.

Alternative 2 would reauthorize the existing land withdrawal and management of BMGR for another 25 years, but the BMGR East boundary would be extended to include the Gila Bend Addition, an area contiguous to and south of the Gila Bend Air Force Auxiliary Field that consists of approximately 2,366 acres of federal public land. USAF and USMC would continue to manage the withdrawn public lands in BMGR East and BMGR West, respectively. The SECAF and SECNAV would continue to consult with the SECDOI before using the BMGR for non-reserved purposes. Alternative 2A would implement Alternative 2 except the period of withdrawal would be for another 50 years. Alternative 2B would implement Alternative 2 except the withdrawal would be for an indefinite period until the BMGR is no longer needed by the USAF and USMC. Alternative 2C would permanently transfer administrative jurisdiction of the lands comprising BMGR East and the Gila Bend Addition to SECAF and BMGR West to SECNAV.

The No Action alternative would consist of Congress not extending the land withdrawal, and the current land withdrawal and reservation would expire in October 2024. Military training and testing use of the range surface would end, including missions involving live-fire use of air-to-air, air-to-ground, ground-to-ground, or ground-to-air munitions. If Congress declines to extend the withdrawal and reservation of the BMGR, responsibility for the formerly withdrawn public lands in the BMGR would revert to Department of the Interior.

The LEIS will consider potential impacts to land use, airspace, safety, noise, hazardous materials and waste, earth resources, water resources, air quality, transportation, wilderness and wilderness study areas, cultural resources, biological resources, socioeconomics, environmental justice, and any additional resources or alternatives identified through the scoping process.

Scoping and Agency Coordination: The scoping process will be used to

involve the public early in the planning and development of the EIS, to help identify issues to be addressed in the environmental analysis. To effectively define the full range of issues and concerns to be evaluated in the LEIS, the USAF and USMC are soliciting scoping comments from interested local, state, and federal agencies and interested members of the public.

Scheduled dates and addresses for meetings will also be published in the *Arizona Daily Star* (Tucson), *Ajo Copper News, Gila Bend Sun, Arizona Republic* (Phoenix metropolitan area), *Casa Grande Dispatch, The Glendale Star, Yuma Sun, Baja El Sol* (Yuma), *La Voz* (Phoenix), and *The Runner* (Tohono O'odham Nation) newspapers a minimum of 15 days prior to each meeting.

Adriane Paris,

Acting Air Force Federal Register Liaison Officer.

[FR Doc. 2020–05576 Filed 3–17–20; 8:45 am]

BILLING CODE 5001–10–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2020–OS–0032]

Privacy Act of 1974; System of Records

AGENCY: Defense Finance and Accounting Service (DFAS), Department of Defense (DoD).

ACTION: Notice of a new System of Records.

SUMMARY: The DFAS proposes to add a System of Records entitled, ''Centralized Disbursing System,'' T7320b. DFAS uses the Centralized Disbursing System (CDS) to process fund disbursements and collections for the Air Force, DFAS Field Sites, Navy Military Sealift Command and the National Geospatial-Intelligence Agency. The system also supports the DFAS centralized environment for disbursing.

DATES: This new System of Records is effective upon publication; however, comments on the Routine Uses will be accepted on or before April 17, 2020. The Routine Uses are effective at the close of the comment period.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

* *Federal Rulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.

* *Mail:* Department of Defense, Office of the Chief Management Officer, Directorate for Oversight and Compliance, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *https://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Mr. Gregory L. Outlaw, DFAS, Freedom of Information/Privacy Act Program Manager, Corporate Communications, DFAS–ZCF/IN, 8899 East 56th Street, Indianapolis, IN 46249–0150 or by telephone at (317) 212–4591.

SUPPLEMENTARY INFORMATION: The CDS was originally designed as a module of the Automated Disbursing System. However, further determination designated this as a separate system. The CDS system handles the disbursement and collection of all funds for these sites except payroll funds. Without the CDS, the impact to agency and military field sites will be untimely processing of payments, and for the interfaces with existing DoD information systems, the inability to balance financial statements and records. The CDS system handles the disbursement and collection of all funds for these agency and military field sites except payroll funds.

The DoD notices for Systems of Records subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address in **FOR FURTHER INFORMATION CONTACT** or at the Defense Privacy, Civil Liberties and Transparency Division website at *https://dpcld.defense.gov*.

The proposed system reports, as required by the Privacy Act, as amended, were submitted on January 14, 2020, to the House Committee on Oversight and Reform, the Senate Committee on Homeland Security and Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to Section 6 of OMB Circular No. A–108, ''Federal Agency Responsibilities for Review, Reporting, and Publication under the Privacy Act,'' revised December 23, 2016 (December 23, 2016, 81 FR 94424).

Dated: March 13, 2020.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

SYSTEM NAME AND NUMBER:

Centralized Disbursing System, T7320b.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Defense Finance and Accounting Service, Disbursing Operations, 8899 East 56th Street, Indianapolis, IN 46249–3300. DISA DECC Ogden, Ogden, UT.

SYSTEM MANAGER(S):

System Manager, 1240 East 9th Street, Cleveland, OH 44199. Telephone: 216–204–2447.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Department of Defense Financial Management Regulation (DoDFMR) 7000.14–R, Vol. 4: 31 U.S.C. Sections 3511 and 3513; and E.O. 9397 (SSN) as amended.

PURPOSE(S) OF THE SYSTEM:

The CDS performs general activities common for disbursing, collecting, payment processing, electronic funds transfer, check issue, printing for legal retention of records and accountability reporting processes. The CDS contains a file control module, which automates manual interfaces with a number of entitlement systems, electronically uploads or rejects data from a single source on a daily basis, and automates the control of daily incoming files. The file control module guarantees data upload into the CDS, ensuring complete and valid voucher data, and returns advice of status to users.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Active Duty and Retired Military Personnel, Air Force National Guard Personnel, DoD Civilian Employees and Federal Contractors.

CATEGORIES OF RECORDS IN THE SYSTEM:

Individual name, Social Security Numbers (SSN), Mailing/Home Address and Financial Information.

RECORD SOURCE CATEGORIES:

Automated Disbursing System, Departmental Cash Management System, Department of Defense Debt Management System, Defense Enterprise Accounting and Management System, Junior Reserve Officers Training Corps Payroll Maintenance and Certification Division, General Accounting and

Finance System, Defense Travel System, General Accounting and Finance System, DFAS Transactional Interface Module, Integrated Accounts Payable System, Military Sealift Command Financial Management System, Reserve Travel System, Standard Material Accounting System, Transportation Financial Management System, Defense Corporate Database/Defense Corporate Warehouse.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

a. To contractors, grantees, experts, consultants, students, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for the federal government when necessary to accomplish an agency function related to this System of Records.

b. To the appropriate Federal, State, local, territorial, tribal, foreign, or international law enforcement authority or other appropriate entity where a record, either alone or in conjunction with other information, indicates a violation or potential violation of law, whether criminal, civil, or regulatory in nature.

c. To any component of the Department of Justice for the purpose of representing the DoD, or its components, officers, employees, or members in pending or potential litigation to which the record is pertinent.

d. In an appropriate proceeding before a court, grand jury, or administrative or adjudicative body or official, when the DoD or other Agency representing the DoD determines that the records are relevant and necessary to the proceeding; or in an appropriate proceeding before an administrative or adjudicative body when the adjudicator determines the records to be relevant to the proceeding.

e. To the National Archives and Records Administration for the purpose of records management inspections conducted under the authority of 44 U.S.C. 2904 and 2906.

f. To a member of Congress or staff acting upon the Member's behalf when the Member or staff requests the information on behalf of, and at the request of, the individual who is the subject of the record.

g. To appropriate agencies, entities, and persons when (1) the DoD suspects or confirms the security or confidentiality of the information in the System of Records; (2) the DoD determined as a result of the suspected or confirmed breach there is a risk of harm to individuals, the DoD (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 DoD's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

h. To another Federal agency or Federal entity, when the DoD 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 in paper and electronic storage media, in accordance with the safeguards mentioned below.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

The records are retrieved primarily by Individual Name, SSN, Mailing/Home Address, and Financial Information.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

System records will be destroyed when 10 years old. After the retention period, records will be destroyed by degaussing, burning, or shredding.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Records are maintained in secure, limited access, and monitored areas. The database is monitored, its access is password protected, and it is Common Access Card (CAC) enabled. Firewalls, Virtual Private Network (VPN) and role based access controls are used. Physical entry by unauthorized persons is restricted through the use of cipher locks, key cards, security guards, closed circuit tv, and identification badges. Archived data is stored on compact discs, or magnetic tapes, which are kept in a locked and controlled access area. Access to personal information is limited to those individuals who require a need to know to perform their official assigned duties.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves in this System of Records should address written inquiries to: Freedom of Information Act/Privacy Act Program Manager, Defense Finance and Accounting Service, 8899 E. 56th Street, Indianapolis, IN 46249–0150. Hours of operation: Monday through Friday, 7:30 a.m. to 4:00 p.m., Eastern Time (ET). FAX: (317) 212–8802. Signed, written requests should include the individual's full name, telephone number, street address, email address, and name and number of this System of Records Notice (SORN). In addition, the requester must provide either a notarized statement or a declaration made in accordance with 28 U.S.C. 1746, using the following format:

If executed outside the United States: ''I declare (or certify, verify, or state) under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on (date). (Signature).''

If executed within the United States, its territories, possessions, or commonwealths: ''I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on (date). (Signature).''

CONTESTING RECORD PROCEDURES:

The DoD rules for accessing records, contesting contents, and appealing initial agency determinations are contained in 32 CFR part 310, or may be obtained from the system manager.

NOTIFICATION PROCEDURES:

Individuals seeking to determine whether information about themselves is contained in this System of Records should address requests to the Freedom of Information/Privacy Act Program Manager, Defense Finance and Accounting Service, Corporate Communications Office, 8899 East 56th Street, Indianapolis, IN 46249–0150. Signed, written requests should contain the individual's full name, telephone number, street address, email address, and name and number of this SORN. In addition, the requester must provide either a notarized statement or an unsworn declaration made in accordance with 28 U.S.C. 1746, in the following format:

If executed outside the United States: ''I declare (or certify, verify, or state) under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on (date). (Signature).''

If executed within the United States, its territories, possessions, or commonwealths: ''I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on (date). (Signature).''

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

N/A.

[FR Doc. 2020–05665 Filed 3–17–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Availability of Record of Decision for the Fallon Range Training Complex Modernization Environmental Impact Statement

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: The United States (U.S.) Department of the Navy (Navy), after carefully weighing the strategic, operational, and environmental consequences of the Proposed Action, announces its decision to select Alternative 3 (Preferred Alternative) from the Fallon Range Training Complex (FRTC) Final Environmental Impact Statement (EIS) Environmental), dated January 2020. This alternative will support the Navy's request for a legislative proposal in the National Defense Authorization Act for Fiscal Year 2021 for Congressional action and Presidential approval for renewal of the current federal land withdrawal and withdrawal of additional federal land to expand the range. It also includes the acquisition of non-federal land. While making this decision, the Navy carefully weighed its strategic and operational needs; potential impacts on the human, natural, and cultural environment; and comments from government officials and agencies, tribal governments, and the public on the proposal and environmental analysis. The Navy selected Alternative 3 because it best meets the purpose of and need for modernization while minimizing impacts on public access and land use. The Navy will implement management practices, monitoring, and mitigation measures to reduce potential impacts of the FRTC modernization.

SUPPLEMENTARY INFORMATION: With the implementation of the modernization, the FRTC significantly enhances the aviation and ground training for a wide range of mission capabilities into the foreseeable future. Modernization of the FRTC will allow the use of precision guided weapons to their required capabilities by Navy aviators, and use of the full complement of weapons by Sea Air and Land (SEAL) teams, protects the capabilities of the aviation electronic warfare range, and modifies existing special use airspace (SUA) to accommodate the additional training capabilities created by modernizing the range complex. In this regard, the Navy's selected alternative, Alternative 3 (Preferred Alternative), fulfills the Navy's execution of its congressionally mandated roles and responsibilities under 10 U.S.C. Section 8062 and 10 U.S.C. Section 167. The complete text of the Record of Decision (ROD) for the FRTC Modernization Final EIS is available on the project website at *www.FRTCModernization.com,* along with the January 2020 FRTC Modernization Final EIS and supporting documents. Single copies of the ROD are available upon request by contacting: Naval Facilities Engineering Command Southwest, Attention: Code EV21.LD, 1220 Pacific Highway, Building 1, 5th Floor, San Diego, CA 92132.

Dated: March 12, 2020.

D.J. Antenucci,

Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 2020–05573 Filed 3–17–20; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF EDUCATION

[Docket No. ED–2020–SCC–0048]

Agency Information Collection Activities; Comment Request; RSA–227, Annual Client Assistance Program Performance Report

AGENCY: Office of Special Education and Rehabilitative Services (OSERS), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension of an existing information collection.

DATES: Interested persons are invited to submit comments on or before May 18, 2020.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2020–SCC–0048. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the *regulations.gov* site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW, LBJ, Room 6W–208D, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact April Trice, 202–245–6074.

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: RSA–227, Annual Client Assistance Program Performance Report.

OMB Control Number: 1820–0528.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 57.

Total Estimated Number of Annual Burden Hours: 912.

Abstract: The Client Assistance Program (CAP) Annual Performance Report (Form RSA–227) will be used to analyze and evaluate the CAP program administered by eligible grantees in states. CAP grantees provide information to individuals with disabilities regarding the services and benefits available under the Rehabilitation Act of 1973 (Rehabilitation Act), as amended by Title IV of the Workforce Innovation and Opportunity Act (WIOA) and the rights afforded them under Title I of the Americans with Disabilities Act. In addition, CAP grantees are authorized to provide advocacy and legal representation to individuals seeking or receiving services under the Rehabilitation Act, in order to resolve disputes with programs providing such services, including vocational rehabilitation services. RSA uses the form to meet specific data collection requirements of Section 112 of the Rehabilitation Act and its implementing Federal Regulations at 34 CFR part 370. CAP grantees must report annually using the RSA–227, which is due on or before December 30 each year.

The collection of information through Form RSA–227 has enabled RSA to furnish the President and Congress with data on the provision of client assistance services and has helped to establish a sound basis for future funding requests. Data is used to indicate trends in the provision of services from year-to-year, as well as evaluate the effectiveness of eligible grantees within individual states in meeting annual priorities and objectives.

The respondents to the RSA–227 is the client assistance program in each year. RSA received recommendations on the initial development of the RSA–227, including the frequency of reporting, from the National Disability Rights Network (NDRN), CAP programs, and other advocacy groups to ensure that the information requested could be provided with minimal burden to the respondents.

Dated: March 13, 2020.

Kate Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer.

[FR Doc. 2020–05635 Filed 3–17–20; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

[FE Docket No. 16–15–LNG]

Eagle LNG Partners Jacksonville LLC; Opinion and Order Granting Long-Term Authorization To Export Liquefied Natural Gas to Non-Free Trade Agreement Nations

AGENCY: Office of Fossil Energy, Department of Energy.

ACTION: Record of decision.

SUMMARY: The Office of Fossil Energy (FE) of the Department of Energy (DOE) gives notice of a Record of Decision (ROD) published under the National Environmental Policy Act of 1969 (NEPA) and implementing regulations. This ROD supports DOE/FE's decision in DOE/FE Order No. 4445, an opinion and order authorizing Eagle LNG Partners Jacksonville LLC to export domestically produced liquefied natural gas (LNG) to non-free trade agreement countries under section 3(a) of the Natural Gas Act (NGA).

FOR FURTHER INFORMATION CONTACT:

Amy Sweeney, U.S. Department of Energy (FE–34) Office of Regulation, Analysis, and Engagement, Office of Fossil Energy, Forrestal Building, Room 3E–042, 1000 Independence Avenue SW, Washington, DC 20585, (202) 586–2627, *Amy.Sweeney@hq.doe.gov.*

Kari Twaite, U.S. Department of Energy (GC–76), Office of the Assistant General Counsel for Electricity and Fossil Energy, Forrestal Building, 1000 Independence Avenue SW, Washington, DC 20585, (202) 586–6978, *Kari.Twaite@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: On October 3, 2019, DOE/FE issued Order No. 4445 to Eagle LNG Partners Jacksonville LLC (Eagle LNG) under NGA section 3(a), 15 U.S.C. 717b(a). This Order authorizes Eagle LNG to export domestically produced LNG to any country with which the United States has not entered into a free trade agreement (FTA) requiring national treatment for trade in natural gas, and with which trade is not prohibited by U.S. law or policy (non-FTA countries). Eagle LNG is authorized to export LNG in a volume equivalent to 49.8 billion cubic feet (Bcf) per year of natural gas (0.14 Bcf/day) from the proposed Jacksonville Project (Project), to be located in Jacksonville, Florida.

DOE/FE participated as a cooperating agency with the Federal Energy Regulatory Commission in preparing an environmental impact statement (EIS) analyzing the potential environmental impacts of the proposed Project that would be used to support the export authorization sought from DOE/FE. DOE adopted the EIS and prepared the ROD, which is attached as an appendix to the Order. The ROD can be found here: *https://www.energy.gov/sites/prod/files/2019/10/f67/ord4445.pdf.*

Signed in Washington, DC, on March 12, 2020.

Amy Sweeney,

Director, Office of Regulation, Analysis, and Engagement, Office of Oil and Natural Gas.

[FR Doc. 2020–05585 Filed 3–17–20; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

[FE Docket No. 15–62–LNG]

Texas LNG Brownsville LLC; Opinion and Order Granting Long-Term Authorization To Export Liquefied Natural Gas to Non-Free Trade Agreement Nations

AGENCY: Office of Fossil Energy, Department of Energy.

ACTION: Record of decision.

SUMMARY: The Office of Fossil Energy (FE) of the Department of Energy (DOE) gives notice of a Record of Decision (ROD) published under the National Environmental Policy Act of 1969 (NEPA) and implementing regulations. This ROD supports DOE/FE's decision in DOE/FE Order No. 4489, an opinion and order authorizing Texas LNG Brownsville LLC to export domestically produced liquefied natural gas (LNG) to non-free trade agreement countries under section 3(a) of the Natural Gas Act (NGA).

FOR FURTHER INFORMATION CONTACT:

Amy Sweeney, U.S. Department of Energy (FE–34), Office of Regulation, Analysis, and Engagement, Office of Fossil Energy, Forrestal Building, Room 3E–042, 1000 Independence Avenue SW, Washington, DC 20585, (202) 586–2627, *Amy.Sweeney@hq.doe.gov.*

Kari Twaite, U.S. Department of Energy (GC–76), Office of the Assistant General Counsel for Electricity and Fossil Energy, Forrestal Building, 1000 Independence Avenue SW, Washington, DC 20585, (202) 586–6978, *Kari.Twaite@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: On February 10, 2020, DOE/FE issued Order No. 4489 to Texas LNG Brownsville LLC (Texas LNG) under NGA section 3(a), 15 U.S.C. 717b(a). This Order authorizes Texas LNG to export domestically produced LNG to any country with which the United States has not entered into a free trade

agreement (FTA) requiring national treatment for trade in natural gas, and with which trade is not prohibited by U.S. law or policy (non-FTA countries). Texas LNG is authorized to export LNG in a volume equivalent to 204.4 billion cubic feet (Bcf) per year of natural gas (0.56 Bcf/day) from the proposed Texas LNG Brownsville LLC Liquefied Natural Gas Export Project (Project), to be located at the Port of Brownsville, Texas.

DOE/FE participated as a cooperating agency with the Federal Energy Regulatory Commission in preparing an environmental impact statement (EIS) analyzing the potential environmental impacts of the proposed Project that would be used to support the export authorization sought from DOE/FE. DOE adopted the EIS and prepared the ROD, which is attached as an appendix to the Order. The ROD can be found here: *https://www.energy.gov/sites/prod/files/2020/02/f71/ord4489.pdf.*

Signed in Washington, DC, on March 12, 2020.

Amy Sweeney,

Director, Office of Regulation, Analysis, and Engagement, Office of Oil and Natural Gas.

[FR Doc. 2020–05583 Filed 3–17–20; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

[FE Docket No. 19–34–LNG]

Annova LNG Common Infrastructure, LLC; Opinion and Order Granting Long-Term Authorization To Export Liquefied Natural Gas to Non-Free Trade Agreement Nations

AGENCY: Office of Fossil Energy, Department of Energy.

ACTION: Record of decision.

SUMMARY: The Office of Fossil Energy (FE) of the Department of Energy (DOE) gives notice of a Record of Decision (ROD) published under the National Environmental Policy Act of 1969 (NEPA) and implementing regulations. This ROD supports DOE/FE's decision in DOE/FE Order No. 4491, an opinion and order authorizing Annova LNG Common Infrastructure, LLC to export domestically produced liquefied natural gas (LNG) to non-free trade agreement countries under section 3(a) of the Natural Gas Act (NGA).

FOR FURTHER INFORMATION CONTACT:

Amy Sweeney, U.S. Department of Energy (FE–34), Office of Regulation, Analysis, and Engagement, Office of Fossil Energy, Forrestal Building, Room 3E–042, 1000 Independence Avenue SW, Washington, DC 20585, (202) 586–2627, *Amy.Sweeney@hq.doe.gov*.

Kari Twaite, U.S. Department of Energy (GC–76), Office of the Assistant General Counsel for Electricity and Fossil Energy, Forrestal Building, 1000 Independence Avenue SW, Washington, DC 20585, (202) 586–6978, *Kari.Twaite@hq.doe.gov*.

SUPPLEMENTARY INFORMATION: On February 10, 2020, DOE/FE issued Order No. 4491 to Annova LNG Common Infrastructure, LLC (Annova) under NGA section 3(a), 15 U.S.C. 717b(a). This Order authorizes Annova to export domestically produced LNG to any country with which the United States has not entered into a free trade agreement (FTA) requiring national treatment for trade in natural gas, and with which trade is not prohibited by U.S. law or policy (non-FTA countries). Annova is authorized to export LNG in a volume equivalent to 360 billion cubic feet (Bcf) per year of natural gas (0.99 Bcf/day) from the proposed Annova LNG Brownsville Project (Project), to be located on the Brownsville Ship Channel in Cameron County, Texas.

DOE/FE participated as a cooperating agency with the Federal Energy Regulatory Commission in preparing an environmental impact statement (EIS) analyzing the potential environmental impacts of the proposed Project that would be used to support the export authorization sought from DOE/FE. DOE adopted the EIS and prepared the ROD, which is attached as an appendix to the Order. The ROD can be found here: *https://www.energy.gov/sites/prod/files/2020/02/f71/ord4491.pdf.*

Signed in Washington, DC, on March 12, 2020.

Amy Sweeney,

Director, Office of Regulation, Analysis, and Engagement, Office of Oil and Natural Gas.

[FR Doc. 2020–05584 Filed 3–17–20; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board Chairs

AGENCY: Office of Environmental Management, Department of Energy.

ACTION: Notice of open meeting: cancellation.

SUMMARY: On March 5, 2020, the Department of Energy published a notice of open meeting announcing a meeting on April 1–2, 2020 of the Environmental Management Site-Specific Advisory Board Chairs. This notice announces the cancellation of this meeting.

DATES: The meeting scheduled for April 1–2, 2020, announced in the March 5, 2020, issue of the **Federal Register** (FR Doc. 2020–04548, 85 FR 12910), is cancelled.

FOR FURTHER INFORMATION CONTACT:

David Borak, EM SSAB Designated Federal Officer, U.S. Department of Energy, 1000 Independence Avenue SW, Washington, DC 20585; Phone: (202) 586–9928; email: *david.borak@em.doe.gov.*

Signed in Washington, DC on March 12, 2020.

LaTanya Butler,

Deputy Committee Management Officer.

[FR Doc. 2020–05587 Filed 3–17–20; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

[FE Docket No. 15–190–LNG]

Rio Grande LNG, LLC; Opinion and Order Granting Long-Term Authorization To Export Liquefied Natural Gas to Non-Free Trade Agreement Nations

AGENCY: Office of Fossil Energy, Department of Energy.

ACTION: Record of decision.

SUMMARY: The Office of Fossil Energy (FE) of the Department of Energy (DOE) gives notice of a Record of Decision (ROD) published under the National Environmental Policy Act of 1969 (NEPA) and implementing regulations. This ROD supports DOE/FE's decision in DOE/FE Order No. 4492, an opinion and order authorizing Rio Grande LNG, LLC to export domestically produced liquefied natural gas (LNG) to non-free trade agreement countries under section 3(a) of the Natural Gas Act (NGA).

FOR FURTHER INFORMATION CONTACT:

Amy Sweeney, U.S. Department of Energy (FE–34), Office of Regulation, Analysis, and Engagement, Office of Fossil Energy, Forrestal Building, Room 3E–042, 1000 Independence Avenue SW, Washington, DC 20585, (202) 586–2627, *Amy.Sweeney@hq.doe.gov.*

Kari Twaite, U.S. Department of Energy (GC–76), Office of the Assistant General Counsel for Electricity and Fossil Energy, Forrestal Building, 1000 Independence Avenue SW, Washington, DC 20585, (202) 586–6978, *Kari.Twaite@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: On February 10, 2020, DOE/FE issued Order No. 4492 to Rio Grande LNG, LLC (Rio Grande LNG) under NGA section 3(a), 15 U.S.C. 717b(a). This Order authorizes Rio Grande LNG to export

domestically produced LNG to any country with which the United States has not entered into a free trade agreement (FTA) requiring national treatment for trade in natural gas, and with which trade is not prohibited by U.S. law or policy (non-FTA countries). Rio Grande LNG is authorized to export LNG in a volume equivalent to 1,318 billion cubic feet (Bcf) per year of natural gas (3.61 Bcf/day) from the proposed Rio Grande LNG Project (Project), to be located on the northern embankment of the Brownsville Ship Channel in Cameron County, Texas.

DOE/FE participated as a cooperating agency with the Federal Energy Regulatory Commission in preparing an environmental impact statement (EIS) analyzing the potential environmental impacts of the proposed Project that would be used to support the export authorization sought from DOE/FE. DOE adopted the EIS and prepared the ROD, which is attached as an appendix to the Order. The ROD can be found here: *https: www.energy.gov/sites/prod/files/2020/02/f71/ord4492.pdf.*

Signed in Washington, DC, on March 12, 2020.

Amy Sweeney,

Director, Office of Regulation, Analysis, and Engagement, Office of Oil and Natural Gas.

[FR Doc. 2020–05588 Filed 3–17–20; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

[FE Docket No. 16–28–LNG]

Venture Global Plaquemines LNG, LLC; Opinion and Order Granting Long-Term Authorization To Export Liquefied Natural Gas to Non-Free Trade Agreement Nations

AGENCY: Office of Fossil Energy, Department of Energy.

ACTION: Record of decision.

SUMMARY: The Office of Fossil Energy (FE) of the Department of Energy (DOE) gives notice of a Record of Decision (ROD) published under the National Environmental Policy Act of 1969 (NEPA) and implementing regulations. This ROD supports DOE/FE's decision in DOE/FE Order No. 4446, an opinion and order authorizing Venture Global Plaquemines LNG, LLC to export domestically produced liquefied natural gas (LNG) to non-free trade agreement countries under section 3(a) of the Natural Gas Act (NGA).

FOR FURTHER INFORMATION CONTACT:

Amy Sweeney, U.S. Department of Energy (FE–34), Office of Regulation, Analysis, and Engagement, Office of Fossil Energy, Forrestal Building, Room 3E–042, 1000 Independence Avenue SW, Washington, DC 20585, (202) 586–2627, *Amy.Sweeney@hq.doe.gov.*

Kari Twaite, U.S. Department of Energy (GC–76), Office of the Assistant General Counsel for Electricity and Fossil Energy, Forrestal Building, 1000 Independence Avenue SW, Washington, DC 20585, (202) 586–6978, *Kari.Twaite@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: On October 16, 2019, DOE/FE issued Order No. 4446 to Venture Global Plaquemines LNG, LLC (Plaquemines LNG) under NGA section 3(a), 15 U.S.C. 717b(a). This Order authorizes Plaquemines LNG to export domestically produced LNG to any country with which the United States has not entered into a free trade agreement (FTA) requiring national treatment for trade in natural gas, and with which trade is not prohibited by U.S. law or policy (non-FTA countries). Plaquemines LNG is authorized to export LNG in a volume equivalent to 1,240 billion cubic feet (Bcf) per year of natural gas (3.40 Bcf/day) from the proposed Plaquemines LNG Project (Project), to be located in Plaquemines Parish, Louisiana.

DOE/FE participated as a cooperating agency with the Federal Energy Regulatory Commission in preparing an environmental impact statement (EIS) analyzing the potential environmental impacts of the proposed Project that would be used to support the export authorization sought from DOE/FE. DOE adopted the EIS and prepared the ROD, which is attached as an appendix to the Order. The ROD can be found here: *https://www.energy.gov/sites/prod/files/2019/10/f67/ord4446.pdf.*

Signed in Washington, DC, on March 12, 2020.

Amy Sweeney,

Director, Office of Regulation, Analysis, and Engagement, Office of Oil and Natural Gas.

[FR Doc. 2020–05586 Filed 3–17–20; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

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

Docket Number: PR20–40–001.

Applicants: Bay Gas Storage Company, LLC.

Description: Tariff filing per 284.123(b),(e)/: Amended 2020 Annual Adjustment to Company Use Percentage to be effective 3/1/2020.

Filed Date: 3/9/2020.

Accession Number: 202003095088.

Comments/Protests Due: 5 p.m. ET 3/30/2020.

Docket Number: PR20–43–000.

Applicants: Columbia Gas of Maryland, Inc.

Description: Tariff filing per 284.123(b),(e)/: CMD SOC Rates effective Feb 19 2020 to be effective 2/19/2020.

Filed Date: 3/9/2020.

Accession Number: 202003095030.

Comments/Protests Due: 5 p.m. ET 3/30/2020.

Docket Numbers: RP19–1523–005.

Applicants: Panhandle Eastern Pipe Line Company, LP.

Description: Compliance filing Compliance with RP19–1523 Order on Technical Conference to be effective 3/1/2020.

Filed Date: 3/11/20.

Accession Number: 20200311–5023.

Comments Due: 5 p.m. ET 3/23/20.

Docket Numbers: RP20–653–000.

Applicants: Tennessee Gas Pipeline Company, L.L.C.

Description: § 4(d) Rate Filing: Abandonment of T–154 in Volume No. 2 to be effective 4/13/2020.

Filed Date: 3/11/20.

Accession Number: 20200311–5001.

Comments Due: 5 p.m. ET 3/23/20.

Docket Numbers: RP20–655–000.

Applicants: Southern Star Central Gas Pipeline, Inc.

Description: § 4(d) Rate Filing: Vol. 2—Negotiated Rate Agreements—BCE-Mach to be effective 2/1/2020.

Filed Date: 3/11/20.

Accession Number: 20200311–5205.

Comments Due: 5 p.m. ET 3/23/20.

The filings are accessible in the Commission's eLibrary system by clicking on the links or 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 date(s). 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: March 12, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–05570 Filed 3–17–20; 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 rate filings:

Docket Numbers: ER19–367–002; ER20–1241–001; ER20–1242–001.
Applicants: Pixelle Specialty Solutions LLC, Pixelle Androscoggin LLC, Pixelle Energy Services LLC.
Description: Notice of Change in Status of the Pixelle MBR Sellers.
Filed Date: 3/11/20.
Accession Number: 20200311–5269.
Comments Due: 5 p.m. ET 4/1/20.

Docket Numbers: ER20–811–001.
Applicants: Wisconsin Public Service Corporation.
Description: Tariff Amendment: Amendment to Filing of Assigned Agreements to be effective 3/17/2020.
Filed Date: 3/12/20.
Accession Number: 20200312–5038.
Comments Due: 5 p.m. ET 4/2/20.

Docket Numbers: ER20–1085–000.
Applicants: Virginia Electric and Power Company, PJM Interconnection, L.L.C.
Description: Supplement to February 24, 2010 Virginia Electric and Power Company tariff filing.
Filed Date: 3/11/20.
Accession Number: 20200311–5271.
Comments Due: 5 p.m. ET 4/1/20.

Docket Numbers: ER20–1241–000.
Applicants: Pixelle Androscoggin LLC.
Description: Baseline eTariff Filing: Notice of Succession to be effective 3/11/2020.
Filed Date: 3/11/20.
Accession Number: 20200311–5131.
Comments Due: 5 p.m. ET 4/1/20.

Docket Numbers: ER20–1242–000.
Applicants: Pixelle Energy Services LLC.
Description: Baseline eTariff Filing: Notice of Succession to be effective 3/11/2020.
Filed Date: 3/11/20.
Accession Number: 20200311–5134.
Comments Due: 5 p.m. ET 4/1/20.

Docket Numbers: ER20–1243–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2020–03–12_SA 3432 MEC-Shenandoah Hillas Wind Project GIA (J476) to be effective 2/26/2020.
Filed Date: 3/12/20.
Accession Number: 20200312–5003.
Comments Due: 5 p.m. ET 4/2/20.

Docket Numbers: ER20–1244–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: Substitute Original 3618 Little Blue Wind, LLC GIA to be effective 12/19/2019.
Filed Date: 3/12/20.
Accession Number: 20200312–5039.
Comments Due: 5 p.m. ET 4/2/20.

Docket Numbers: ER20–1245–000.
Applicants: Duke Energy Carolinas, LLC, Duke Energy Florida, LLC.
Description: § 205(d) Rate Filing: DEF Storm Recovery to be effective 6/1/2020.
Filed Date: 3/12/20.
Accession Number: 20200312–5060.
Comments Due: 5 p.m. ET 4/2/20.

Docket Numbers: ER20–1246–000.
Applicants: NorthWestern Corporation.
Description: § 205(d) Rate Filing: RS 42–SD—EP&C Agreement with East River Electric Power Cooperative to be effective 3/14/2020.
Filed Date: 3/12/20.
Accession Number: 20200312–5070.
Comments Due: 5 p.m. ET 4/2/20.

Docket Numbers: ER20–1247–000.
Applicants: GenOn Wholesale Generation, LP.
Description: Tariff Cancellation: Notice of Cancellation to be effective 3/13/2020.
Filed Date: 3/12/20.
Accession Number: 20200312–5075.
Comments Due: 5 p.m. ET 4/2/20.

Docket Numbers: ER20–1248–000.
Applicants: GenOn Energy Management, LLC.
Description: § 205(d) Rate Filing: Market-Based Rate Tariff Revisions to be effective 3/13/2020.
Filed Date: 3/12/20.
Accession Number: 20200312–5096.
Comments Due: 5 p.m. ET 4/2/20.

Docket Numbers: ER20–1249–000.
Applicants: Northern States Power Company, a Minnesota corporation, Northern States Power Company, a Wisconsin corporation.
Description: § 205(d) Rate Filing: 2020 Interchange Agreement Annual Filing to be effective 1/1/2020.
Filed Date: 3/12/20.
Accession Number: 20200312–5111.
Comments Due: 5 p.m. ET 4/2/20.

Docket Numbers: ER20–1250–000.
Applicants: Brunot Island Power, LLC.
Description: § 205(d) Rate Filing: Market-Based Rate Tariff Revisions to be effective 3/13/2020.
Filed Date: 3/12/20.
Accession Number: 20200312–5127.
Comments Due: 5 p.m. ET 4/2/20.

Docket Numbers: ER20–1251–000.
Applicants: Gilbert Power, LLC.
Description: § 205(d) Rate Filing: Market-Based Rate Tariff Revisions to be effective 3/13/2020.
Filed Date: 3/12/20.
Accession Number: 20200312–5130.
Comments Due: 5 p.m. ET 4/2/20.

Docket Numbers: ER20–1252–000.
Applicants: Mountain Power, LLC.
Description: § 205(d) Rate Filing: Market-Based Rate Tariff Revisions to be effective 3/13/2020.
Filed Date: 3/12/20.
Accession Number: 20200312–5131.
Comments Due: 5 p.m. ET 4/2/20.

Docket Numbers: ER20–1253–000.
Applicants: New Castle Power, LLC.
Description: § 205(d) Rate Filing: Market-Based Rate Tariff Revisions to be effective 3/13/2020.
Filed Date: 3/12/20.
Accession Number: 20200312–5134.
Comments Due: 5 p.m. ET 4/2/20.

Docket Numbers: ER20–1254–000.
Applicants: Portland Power, LLC.
Description: § 205(d) Rate Filing: Market-Based Rate Tariff Revisions to be effective 3/13/2020.
Filed Date: 3/12/20.
Accession Number: 20200312–5138.
Comments Due: 5 p.m. ET 4/2/20.

Docket Numbers: ER20–1255–000.
Applicants: Sayreville Power, LLC.
Description: § 205(d) Rate Filing: Market-Based Rate Tariff Revisions to be effective 3/13/2020.
Filed Date: 3/12/20.
Accession Number: 20200312–5139.
Comments Due: 5 p.m. ET 4/2/20.

Docket Numbers: ER20–1256–000.
Applicants: Shawville Power, LLC.
Description: § 205(d) Rate Filing: Market-Based Rate Tariff Revisions to be effective 3/13/2020.
Filed Date: 3/12/20.
Accession Number: 20200312–5142.
Comments Due: 5 p.m. ET 4/2/20.

Docket Numbers: ER20–1257–000.
Applicants: Warren Generation, LLC.
Description: § 205(d) Rate Filing: Market-Based Rate Tariff Revisions to be effective 3/13/2020.
Filed Date: 3/12/20.
Accession Number: 20200312–5144.
Comments Due: 5 p.m. ET 4/2/20.

The filings are accessible in the Commission's eLibrary system by clicking on the links or 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: March 12, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–05565 Filed 3–17–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. CP10–22–000, CP16–18–000, and CP20–77–000]

Magnum Gas Storage, LLC; Notice of Motion To Partially Vacate Certificate Authorization or in the Alternative, Motion To Amend Certificate Authorization

Take notice that on March 4, 2020, Magnum Gas Storage, LLC (Magnum), 3165 E Millrock Dr., #330, Holladay, Utah 84121, filed in Docket No. CP20–77–000, a Motion requesting to partially vacate the certificate authorization for certain facilities approved in the captioned dockets, or in the alternative to amend the certificate authorization. Magnum proposes to delete two natural gas storage caverns, one brine pond and related facilities from the current authorization as they are no longer needed for the authorized storage service. Magnum states that no facilities authorized in the above captioned proceedings have been constructed, or placed into service, all as more fully set forth in the application, which is on file with the Commission and open to public inspection. The filing may also be viewed on the web at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (866) 208–3676 or TTY, (202) 502–8659.

Any questions regarding this application should be directed to John Alvarado, CFO/COO, Magnum Development LLC, 3165 E Millrock Dr., #330, Holladay, Utah 84121, telephone: (801) 748–5567, email: *jalvarado@magnumdev.com* or J. Gordon Pennington, Attorney at Law, Georgetown Place, 1101 30th Street NW, Suite 500, Washington, DC 20007, phone: (202) 625–4330, email: *Pennington5@verizon.net.*

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below, file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 3 copies of filings made with the Commission and must provide a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

As of the February 27, 2018 date of the Commission's order in Docket No. CP16–4–001, the Commission will apply its revised practice concerning out-of-time motions to intervene in any new Natural Gas Act section 3 or section 7 proceeding.[1] Persons desiring to become a party to a certificate proceeding are to intervene in a timely manner. If seeking to intervene out-of-time, the movant is required to show good cause why the time limitation should be waived, and should provide justification by reference to factors set forth in Rule 214(d)(1) of the Commission's Rules and Regulations.[2]

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 should submit an original and 3 copies of the protest or intervention to the Federal Energy regulatory Commission, 888 First Street NE, Washington, DC 20426.

Comment Date: 5:00 p.m. Eastern Time on March 27, 2020.

Dated: March 12, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–05566 Filed 3–17–20; 8:45 am]

BILLING CODE 6717–01–P

[1] *Tennessee Gas Pipeline Company, L.L.C.,* 162 FERC 61,167 at 50 (2018).

[2] 18 CFR 385.214(d)(1).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. AD20–3–000]

Review of Cost Submittals by Other Federal Agencies for Administering Part I of the Federal Power Act; Notice of Technical Conference

In an order issued on October 8, 2004, the Commission set forth a guideline for Other Federal Agencies (OFAs) to submit their costs related to Administering Part I of the Federal Power Act. *Order On Rehearing Consolidating Administrative Annual Charges Bill Appeals And Modifying Annual Charges Billing Procedures,* 109 FERC 61,040 (2004) (October 8 Order). The Commission required OFAs to submit their costs using the OFA Cost Submission Form. The October 8 Order also announced that a technical conference would be held for the purpose of reviewing the submitted cost forms and detailed supporting documentation.

The Commission will hold a technical conference, via conference call, at the time identified below. The technical conference will address the accepted costs submitted by the OFAs. The purpose of the conference will be for OFAs and licensees to discuss costs reported in the forms and any other supporting documentation or analyses.

The technical conference will also be transcribed. Those interested in obtaining a copy of the transcript immediately for a fee should contact the Ace-Federal Reporters, Inc., at 202–347–3700, or 1–800–336–6646. Two weeks after the post-forum meeting, the

transcript will be available for free on the Commission's e-library system. Anyone without access to the Commission's website or who has questions about the technical conference should contact Raven A. Rodriguez at (202) 502–6276 or via email at *annualcharges@ferc.gov.*

FERC conferences are accessible under section 508 of the Rehabilitation Act of 1973. For accessibility accommodations please send an email to *accessibility@ferc.gov* or call toll free (866) 208–3372 (voice), (202) 208–8659 (TTY), or send a FAX to 202–208–2106 with the required accommodations.

Technical Conference Call

Date: Thursday, March 26, 2020
Time: 2:00p.m.–4:00p.m. (EST)

Conference Call-in Information:

Webex

Call-in number: 202–502–8001
Meeting ID number: 997 607 833
Access Code: 997 607 833

Dated: March 12, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–05568 Filed 3–17–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2804–000]

Goose River Hydro, Inc.; Notice of Authorization for Continued Project Operation

On February 2, 2018, Goose River Hydro, Inc., licensee for the Goose River Hydroelectric Project, filed an Application for a New License pursuant to the Federal Power Act (FPA) and the Commission's regulations thereunder. The Goose River Hydroelectric Project is located near Belfast, Waldo County, Maine.

The license for Project No. 2804 was issued for a period ending February 29, 2020. Section 15(a)(1) of the FPA, 16 U.S.C. 808(a)(1), requires the Commission, at the expiration of a license term, to issue from year-to-year an annual license to the then licensee under the terms and conditions of the prior license until a new license is issued, or the project is otherwise disposed of as provided in section 15 or any other applicable section of the FPA. If the project's prior license waived the applicability of section 15 of the FPA, then, based on section 9(b) of the Administrative Procedure Act, 5 U.S.C. 558(c), and as set forth at 18 CFR 16.21(a), if the licensee of such project has filed an application for a subsequent license, the licensee may continue to operate the project in accordance with the terms and conditions of the license after the minor or minor part license expires, until the Commission acts on its application. If the licensee of such a project has not filed an application for a subsequent license, then it may be required, pursuant to 18 CFR 16.21(b), to continue project operations until the Commission issues someone else a license for the project or otherwise orders disposition of the project.

If the project is subject to section 15 of the FPA, notice is hereby given that an annual license for Project No. 2804 is issued to Goose River Hydro, Inc. for a period effective March 1, 2020 through February 28, 2021, or until the issuance of a new license for the project or other disposition under the FPA, whichever comes first. If issuance of a new license (or other disposition) does not take place on or before February 28, 2021, notice is hereby given that, pursuant to 18 CFR 16.18(c), an annual license under section 15(a)(1) of the FPA is renewed automatically without further order or notice by the Commission, unless the Commission orders otherwise.

If the project is not subject to section 15 of the FPA, notice is hereby given that the Goose River Hydro, Inc. is authorized to continue operation of the Goose River Hydroelectric Project, until such time as the Commission acts on its application for a subsequent license.

Dated: March 12, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–05567 Filed 3–17–20; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–ORD–2015–0365; FRL 10006–09–ORD]

Board of Scientific Counselors (BOSC) Air and Energy Subcommittee Meeting—April 2020

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public meeting.

SUMMARY: The Environmental Protection Agency (EPA), Office of Research and Development (ORD), gives notice of a meeting of the Board of Scientific Counselors (BOSC) Air and Energy (A–E) Subcommittee to discuss the initial progress on implementation of the A–E Strategic Research Action Plan (StRAP).

DATES: The meeting will be held on Wednesday, April 1, 2020, from 8:30 a.m. to 5 p.m. (EST) and will continue on Thursday, April 2, 2020, from 8:30 a.m. to 5 p.m. (EST) and Friday, April 3, 2020, from 8:30 a.m. to 1 p.m. (EST). Meeting times are subject to change. This meeting is open to the public. Those who wish to attend must register by March 25, 2020. Comments must be received by March 25, 2020 to be considered by the subcommittee. Requests for the draft agenda or making a presentation at the meeting will be accepted until March 30, 2020.

ADDRESSES: The meeting will be held at the EPA's Research Triangle Park Main Campus Facility, Room C–114, 109 T.W. Alexander Drive, Research Triangle Park, North Carolina 27711. Attendees should register at *https://epa-bosc-a-e.eventbrite.com* by March 25, 2020.

Submit your comments to Docket ID No. EPA–HQ–ORD–2015–0365 by one of the following methods:

- *www.regulations.gov:* Follow the online instructions for submitting comments.
  - Note: comments submitted to the *www.regulations.gov* website are anonymous unless identifying information is included in the body of the comment.
- *Email:* Send comments by electronic mail (email) to: *ORD.Docket@epa.gov,* Attention Docket ID No. EPA–HQ–ORD–2015–0365.
  - Note: comments submitted via email are not anonymous. The sender's email will be included in the body of the comment and placed in the public docket which is made available on the internet.
- *Fax:* Fax comments to: (202) 566–0224, Attention Docket ID No. EPA–HQ–ORD–2015–0365.
- *Mail:* Send comments by mail to: Board of Scientific Counselors (BOSC) Air and Energy Subcommittee Docket, EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Ave. NW, Washington, DC 20004, Attention Docket ID No. EPA–HQ–ORD–2015–0365.
- *Hand Delivery or Courier:* Deliver comments to: EPA Docket Center (EPA/DC), Room 3334, WJC West Building, 1301 Constitution Ave. NW, Washington, DC 20004, Attention Docket ID No. EPA–HQ–ORD–2015–0365.
  - Note: this is not a mailing address. Deliveries are only accepted during the docket center's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: All comments received, including any personal information provided, will be included in the public docket without change and may be made available online at *www.regulations.gov.* Information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute will not be included in the public docket, and should not be submitted through *www.regulations.gov* or email. For additional information about the EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/dockets/.*

Public Docket: Publicly available docket materials may be accessed

- *Online* at *www.regulations.gov*.
- *Hard Copy* at the Board of Scientific Counselors Executive Committee Docket,
- EPA/Docket Center Reading Room, William Jefferson Clinton West Building, Room 3334, 1301 Constitution Ave. NW, Washington, DC 20004, Hours: 8:30 a.m. to 4:30 p.m., Monday–Friday, Telephone: (202) 566–1744.

Copyrighted materials in the docket are only available via hard copy. The telephone number for the ORD Docket is (202) 566–1752.

FOR FURTHER INFORMATION CONTACT: The Designated Federal Officer (DFO) via mail at: Tom Tracy, Mail Code 8104R, Office of Science Policy, Office of Research and Development, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; via phone/voice mail at: (202) 564–6518; via fax at: (202) 565–2911; or via email at: *tracy.tom@epa.gov.*

Any member of the public interested in receiving a draft agenda, attending the meeting, or making a presentation at the meeting may contact Tom Tracy.

SUPPLEMENTARY INFORMATION: The Board of Scientific Counselors (BOSC) is a federal advisory committee that provides advice and recommendations to EPA's Office of Research and Development on technical and management issues of its research programs. Meeting agenda and materials will be posted to *https://www.epa.gov/bosc.* Proposed agenda items for the meeting include but are not limited to the following: A–E program overview, emerging risks, and PFAS.

Information on Services Available: For information on translation services, access, or services for individuals with disabilities, please contact Tom Tracy at (202) 564–6518 or *tracy.tom@epa.gov.* To request accommodation of a disability, please contact Tom Tracy at least ten days prior to the meeting to give the EPA adequate time to process your request.

Authority: Pub. L. 92–463, § 1, Oct. 6, 1972, 86 Stat. 770.

Dated: March 10, 2020.

Mary Ross,

Director, Office of Science Advisor, Policy, and Engagement.

[FR Doc. 2020–05579 Filed 3–17–20; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments, relevant information, or documents regarding the agreements to the Secretary by email at *Secretary@fmc.gov,* or by mail, Federal Maritime Commission, Washington, DC 20573. Comments will be most helpful to the Commission if received within 12 days of the date this notice appears in the **Federal Register**. Copies of agreements are available through the Commission's website (*www.fmc.gov*) or by contacting the Office of Agreements at (202)-523–5793 or *tradeanalysis@fmc.gov.*

Agreement No.: 201335.

Agreement Name: Crowley/Seaboard Trinidad Space Charter Agreement.

Parties: Crowley Caribbean Services LLC and Seaboard Marine Ltd.

Filing Party: Wayne Rohde; Cozen O'Connor.

Synopsis: The Agreement authorizes Seaboard to charter space to Crowley in the trade between Miami, FL and Trinidad.

Proposed Effective Date: 4/26/2020.

Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/27481.

Dated: March 13, 2020.

Rachel E. Dickon,

Secretary.

[FR Doc. 2020–05596 Filed 3–17–20; 8:45 am]

BILLING CODE 6731–AA–P

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

Sunshine Act Notice; Cancellation of Meeting Notice

Date: March 16, 2020.

The following Commission meeting has been cancelled. No earlier announcement of the cancellation was possible.

TIME AND DATE: 10:00 a.m., Thursday, March 19, 2020.

PLACE: The Richard V. Backley Hearing Room, Room 511N, 1331 Pennsylvania Avenue NW, Washington, DC 20004 (enter from F Street entrance).

STATUS: Open.

MATTERS TO BE CONSIDERED: The Commission will consider and act upon the following in open session: *Secretary of Labor* v. *Northshore Mining Co.,* Docket Nos. LAKE 2017–224, et al. (Issues include whether the Judge erred in concluding that a violation of the walkway standard resulted from an unwarrantable failure and the operator's reckless disregard.)

Any person attending this meeting who requires special accessibility features and/or auxiliary aids, such as sign language interpreters, must inform the Commission in advance of those needs. Subject to 29 CFR 2706.150(a)(3) and § 2706.160(d).

CONTACT PERSON FOR MORE INFO: Emogene Johnson (202) 434–9935/(202) 708–9300 for TDD Relay/1–800–877–8339 for toll free.

PHONE NUMBER FOR LISTENING TO MEETING: 1–(866) 236–7472, Passcode: 678–100.

Authority: 5 U.S.C. 552b.

Dated: March 16, 2020.

Sarah L. Stewart,

Deputy General Counsel.

[FR Doc. 2020–05761 Filed 3–16–20; 4:15 pm]

BILLING CODE 6735–01–P

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

Sunshine Act Notice; Cancellation of Meeting Notice

March 16, 2020.

The following Commission oral argument has been cancelled. No earlier announcement of the cancellation was possible.

TIME AND DATE: 10:00 a.m., Wednesday, March 18, 2020.

PLACE: The Richard V. Backley Hearing Room, Room 511N, 1331 Pennsylvania Avenue NW, Washington, DC 20004 (enter from F Street entrance).

STATUS: Open.

MATTERS TO BE CONSIDERED: The Commission will hear oral argument in the matter *Secretary of Labor* v. *Northshore Mining Co.,* Docket Nos. LAKE 2017–224, et al. (Issues include whether the Judge erred in concluding that a violation of the walkway standard resulted from an unwarrantable failure and the operator's reckless disregard.)

Any person attending this meeting who requires special accessibility features and/or auxiliary aids, such as

sign language interpreters, must inform the Commission in advance of those needs. Subject to 29 CFR 2706.150(a)(3) and § 2706.160(d).

CONTACT PERSON FOR MORE INFO: Emogene Johnson (202) 434–9935/(202) 708–9300 for TDD Relay/1–800–877–8339 for toll free.

PHONE NUMBER FOR LISTENING TO MEETING: 1–(866) 236–7472, Passcode: 678–100.

Authority: 5 U.S.C. 552b.

Dated: March 16, 2020.

Sarah L. Stewart,

Deputy General Counsel.

[FR Doc. 2020–05760 Filed 3–16–20; 4:15 pm]

BILLING CODE 6735–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

RIN 3064–ZA15

FEDERAL RESERVE SYSTEM

[Docket No. OP–1699]

Guidance for Resolution Plan Submissions of Certain Foreign-Based Covered Companies

AGENCY: Board of Governors of the Federal Reserve System (Board) and Federal Deposit Insurance Corporation (FDIC).

ACTION: Proposed guidance; request for comments.

SUMMARY: The Board and the FDIC (together, the ''agencies'') are inviting comments on proposed guidance for the 2021 and subsequent resolution plan submissions by certain foreign banking organizations (''FBOs''). The proposed guidance is meant to assist these firms in developing their resolution plans, which are required to be submitted pursuant to Section 165(d) of the Dodd-Frank Wall Street Reform and Consumer Protection Act (the ''Dodd-Frank Act''). The scope of application of the proposed guidance would be FBOs that are triennial full filers and whose intermediate holding companies (''U.S. IHCs'') have a score of 250 or more under the second methodology (''method 2'') of the global systemically important bank (''GSIB'') surcharge framework. The proposed guidance, which is largely based on prior guidance, describes the agencies' expectations regarding a number of key vulnerabilities in plans for a rapid and orderly resolution under the U.S. Bankruptcy Code (*i.e.,* capital; liquidity; governance mechanisms; operational; legal entity rationalization and separability; and derivatives and trading activities). The proposed guidance also updates certain aspects of prior guidance based, in part, on the agencies' review of certain FBOs' most recent resolution plan submissions and changes to the resolution planning rule. The agencies invite public comment on all aspects of the proposed guidance.

DATES: Comments should be received on or before May 5, 2020.

ADDRESSES: Interested parties are encouraged to submit written comments jointly to both agencies. Comments should be directed to:

Board: You may submit comments, identified by Docket No. OP–1699, by any of the following methods:

- *Agency website: http://www.federalreserve.gov.* Follow the instructions for submitting comments at *http://www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm.*
- *Email: regs.comments@federalreserve.gov.* Include docket number in the subject line of the message.
- *Fax:* (202) 452–3819 or (202) 452–3102.
- *Mail:* Ann E. Misback, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.

All public comments will be made available on the Board's website at *http://www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfms* as submitted, unless modified for technical reasons or to remove personal information at the commenter's request. Accordingly, comments will not be edited to remove any identifying or contact information. Public comments may also be viewed electronically or in paper form in Room 146, 1709 New York Avenue NW, Washington, DC 20006, between 9:00 a.m. and 5:00 p.m. on weekdays.

FDIC: You may submit comments, identified by RIN 3064–ZA15, by any of the following methods:

- *Agency website: https://www.fdic.gov/regulations/laws/federal.* Follow the instructions for submitting comments on the Agency website.
- *Email: comments@fdic.gov.* Include ''RIN 3064–ZA15'' on the subject line of the message.
- *Mail:* Executive Secretary, Attention: Comments, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.
- *Hand Delivery/Courier:* Guard station at the rear of the 550 17th Street NW Building (located on F Street) on business days between 7 a.m. and 5 p.m.
- *Public Inspection:* All comments received, including any personal information provided, will be posted generally without change to *https://www.fdic.gov/regulations/laws/federal.*

FOR FURTHER INFORMATION CONTACT:

Board: Mona Elliot, Deputy Associate Director, (202) 452–4688, Division of Supervision and Regulation, Laurie Schaffer, Deputy General Counsel, (202) 452–2272, Jay Schwarz, Special Counsel, (202) 452–2970, Steve Bowne, Senior Counsel, (202) 452–3900, or Sarah Podrygula, Attorney (202) 912–4658, Legal Division. Users of Telecommunications Device for the Deaf (TDD) may call (202) 263–4869.

FDIC: Alexandra Steinberg Barrage, Associate Director, Policy and Data Analytics, *abarrage@fdic.gov;* Heidilynne Schultheiss, Chief, Resolution Strategy Section, *hschultheiss@fdic.gov;* Yan Zhou, Chief, Supervisory Programs Section, *yazhou@fdic.gov;* Ronald W. Crawley, Jr., Senior Resolution Policy Specialist, *rcrawley@fdic.gov,* Division of Complex Institution Supervision and Resolution; David N. Wall, Assistant General Counsel, *dwall@fdic.gov;* Celia Van Gorder, Supervisory Counsel, *cvangorder@fdic.gov;* or Esther Rabin, Counsel, *erabin@fdic.gov,* Legal Division, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

SUPPLEMENTARY INFORMATION:

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II. Overview of the Proposed Guidance
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I. Background

Section 165(d) of the Dodd-Frank Act [1] and the jointly issued implementing regulation [2] require certain financial companies, including certain foreign-based firms, to report periodically to the Board and the FDIC their plans for rapid and orderly resolution under the U.S. Bankruptcy Code (the ''Bankruptcy Code'') in the event of material financial distress or failure. With respect to a covered company [3] that is organized or incorporated in a jurisdiction other than the United States or that is an FBO, the Rule requires that the firm's U.S. resolution plan include specified information with respect to the

[1] 12 U.S.C. 5365(d).

[2] 12 CFR part 243 and 12 CFR part 381 (the ''Rule''), as amended.

[3] The terms ''covered company,'' ''material entities,'' ''identified critical operations,'' ''core business lines,'' and similar terms used throughout the proposal all have the same meaning as in the Rule.

subsidiaries, branches, and agencies, and identified critical operations and core business lines, as applicable, that are domiciled in the United States or conducted in whole or material part in the United States.[4] The Rule also requires, among other things, each financial company's full resolution plan to include a strategic analysis of the plan's components, a description of the range of specific actions the company proposes to take in resolution, and a description of the company's organizational structure, material entities, and interconnections and interdependencies.[5] In addition, the Rule requires that all resolution plans include a confidential section that contains any confidential supervisory and proprietary information submitted to the Board and the FDIC and a section that the agencies make available to the public. Public sections of resolution plans can be found on the agencies' websites.[6]

Objectives of the Resolution Planning Process

The goal of the Dodd-Frank Act resolution planning process is to help ensure that a covered company's failure would not have serious adverse effects on financial stability in the United States. Specifically, the resolution planning process requires covered companies to demonstrate that they have adequately assessed the challenges that their structures and business activities pose to resolution and that they have taken action to address those issues. For FBOs, the resolution planning process focuses on their U.S. subsidiaries and operations.

The agencies believe that the preferred resolution outcome for many FBOs is a successful home country resolution using a single point of entry (''SPOE'') resolution strategy where U.S. material entities are provided with sufficient capital and liquidity resources to allow them to stay out of resolution proceedings and maintain continuity of operations throughout the parent's resolution. However, since support from the foreign parent in stress cannot be ensured, the Rule provides that the U.S. resolution plan for foreign-based covered companies should specifically address a scenario where the U.S. operations experience material financial distress and not assume that the covered company takes resolution actions outside the United States that would eliminate the need for any U.S. subsidiaries to enter resolution proceedings.[7] Nonetheless, the Rule also provides firms with appropriate flexibility to construct a U.S. resolution strategy in a way that is not inconsistent with a firm's global resolution strategy, as long as those assumptions support the firms' U.S. resolution strategy and adhere to the assumptions articulated in the Rule.

Recent Developments

Implementation of the Rule has been an iterative process aimed at strengthening the resolution planning capabilities of financial institutions subject to the Rule. The agencies have previously provided guidance and other feedback on several occasions to certain FBOs.[8] In general, the guidance and feedback were intended to assist the recipients in their development of future resolution plan submissions and to provide additional clarity with respect to the agencies' expectations for the filers' future progress.

The agencies are now proposing to update aspects of the *Guidance for 2018 § 165(d) Annual Resolution Plan Submissions By Foreign-based Covered Companies that Submitted Resolution Plans in July 2015* (''2018 FBO guidance'').[9] The 2018 FBO guidance was provided to four FBOs.[10]

Several developments inform the proposed guidance:

- The agencies' review of certain FBOs' most recent resolution plan submissions and the issuance of individual letters communicating the agencies' views on and shortcomings contained in the 2018 resolution plans filed by the firms subject to the 2018 FBO guidance (''2018 feedback letters'');[11]
- Revisions to the content related to payment, clearing, and settlement activities (''PCS'') and derivatives and trading activities (''DER'') in the updated guidance for the resolution plan submissions by the eight largest, most complex U.S. banking organizations in February 2019 (''2019 domestic guidance'');[12] and
- The 2019 amendments to the Rule (''2019 revisions'').[13]

In December 2018, the agencies issued the 2018 feedback letters, which communicated their views on and identified shortcomings contained in the 2018 resolution plans filed by the firms subject to the 2018 FBO guidance. These letters also described the meaningful resolvability improvements made by the FBOs. The FBOs that received this feedback are expected to address their shortcomings and complete the enhancement initiatives described in their 2018 resolution plans by July 1, 2020, as provided in the 2018 feedback letters and confirmed by the letters issued to the firms on July 26, 2019.[14] The review of the resolution plan submissions that resulted in the 2018 feedback letters helped to inform changes to the 2018 FBO guidance, as described below.

In February 2019, the agencies released the 2019 domestic guidance, which reiterated the agencies' expectations for eight domestic firms regarding several elements of their resolution plans and made material updates to guidance relating to PCS and DER. As described below, the agencies are proposing updates to the 2018 FBO guidance regarding PCS and DER, which will more closely align the agencies' expectations in these areas with the expectations described in the 2019 domestic guidance, taking into account issues specific to FBOs. The 2019 domestic guidance also consolidated all prior guidance applicable to the eight firms to which it was directed. In the consultation period for the 2019 domestic guidance, the agencies received comments supporting the consolidation efforts and subsequently indicated their intent to similarly consolidate and request public comment on the 2018 FBO guidance. Accordingly, the agencies are proposing to consolidate and supersede all prior

[4] 12 CFR 243.5(a)(2)(i); 12 CFR 381.5(a)(2)(i).

[5] Under the Rule, all filers must submit a full resolution plan, either every other time a resolution plan submission is required or as a firm's initial resolution plan submission. *See* 12 CFR 243.4(a)(5)–(6), (b)(4)–(5), and (c)(4)–(5); 12 CFR 381.4(a)(5)–(6), (b)(4)–(5), and (c)(4)–(5).

[6] The public sections of resolution plans submitted to the agencies are available at *https://www.federalreserve.gov/supervisionreg/resolution-plans.htm* and *www.fdic.gov/regulations/reform/resplans/.*

[7] 12 CFR 243.4(h)(3); 12 CFR 381.4(h)(3). Presently, the U.S. resolution strategy of each firm that would be subject to the proposed guidance is a U.S. SPOE resolution strategy, which is designed to have the U.S. IHC recapitalize and provide financial resources to its material entity subsidiaries prior to entering U.S. bankruptcy proceedings.

[8] *See infra* III. *Consolidation of Prior Guidance.*

[9] Available at *www.federalreserve.gov/newsevents/pressreleases/files/bcreg20170324a21.pdf* and *www.fdic.gov/resauthority/2018subguidance.pdf.*

[10] Barclays PLC, Credit Suisse Group AG, Deutsche Bank AG, and UBS AG.

[11] Available at *www.federalreserve.gov/newsevents/pressreleases/bcreg20181220c.htm.*

[12] Final Guidance for the 2019, 84 FR 1438 (February 4, 2019).

[13] Resolution Plans Required, 84 FR 59194 (November 1, 2019). The amendments became effective on December 31, 2019.

[14] *See https://www.federalreserve.gov/newsevents/pressreleases/bcreg20190726a.htm.* For clarity, the shortcoming(s) and the remaining project(s) identified for each firm that would be subject to the proposed guidance in its 2018 feedback letter should be addressed as set forth in each firm's respective 2018 feedback letter, notwithstanding the consolidation of all relevant prior guidance into the proposed guidance.

resolution planning guidance that has been directed to the FBOs to which this guidance is proposed to apply (''Specified FBOs'' or ''firms'').

More recently, in November 2019, the agencies finalized the 2019 revisions, which amended the Rule to address changes to the Dodd-Frank Act made by the Economic Growth, Regulatory Relief, and Consumer Protection Act (''EGRRCPA'') [15] and improve certain aspects of the Rule based on the agencies' experience implementing the Rule since its adoption. Among other things, the 2019 revisions modified the scope of application of the resolution planning requirement, the frequency of resolution plan submissions, informational content requirements (primarily through the introduction of new plan types), and the Rule's procedures for the identification of critical operations. Consistent with EGRRCPA, the 2019 revisions applied the resolution planning requirement to financial institutions that would be subject to category I, II, or III standards under the ''domestic tailoring rule'' or the ''foreign banking organization rule'' (together with the domestic tailoring rule, the ''tailoring rules'') [16] and certain other covered companies.

Under the 2019 revisions and the proposed scope of guidance, each Specified FBO would be a triennial full filer and will be required to submit a resolution plan every three years, alternating between a full resolution plan and a targeted resolution plan. The 2019 revisions require all triennial full filers to submit a targeted resolution plan on or before July 1, 2021, followed by a full resolution plan in 2024.

In addition, the agencies indicated in the 2019 revisions that they would strive to provide final general guidance at least a year before the next resolution plan submission date of firms to which the general guidance is directed. The 2019 revisions also provided certain technical changes, including the clarification that FBOs should not assume that the foreign parent company takes resolution actions outside of the United States that would eliminate the need for any U.S. subsidiaries to enter into resolution proceedings.

International Cooperation on Resolution Planning

The 2018 feedback letters also noted the importance of the agencies' engagement with non-U.S. regulators. The Specified FBOs are subject to their home country resolvability expectations, in addition to section 165(d) of the Dodd-Frank Act and the Rule. Resolution of the U.S. operations of a firm domiciled outside the United States with significant global activities (*i.e.,* the Specified FBOs) will require substantial coordination between home and host country authorities. The agencies identified three areas in the 2018 feedback letters (legal entity rationalization; PCS; and derivatives booking practices) where enhanced cooperation between the agencies and each firm's home regulatory authorities would maximize resolvability under both the U.S. and home country resolution strategies.[17] The agencies will continue to coordinate with non-U.S. authorities regarding these and other resolution matters (*e.g.,* resources in resolution, communications), including developments in the U.S. and home country resolution capabilities of the Specified FBOs.

Capital and Liquidity

The agencies received several comments on an array of resolution capital and liquidity issues during consideration of the 2019 domestic guidance, but declined to adopt any modifications in the final version.[18] Instead, the agencies indicated that they would continue to consider those comments, coordinate with non-U.S. regulators, and provide additional information in the future on those topics. The agencies continue to evaluate the capital and liquidity guidance and expect that any future actions in these areas, whether guidance or rules, would be adopted through notice and comment procedures, which would provide an opportunity for public input. The agencies further expect to collaborate in taking such actions in a manner consistent with the Board's Total Loss-Absorbing Capacity rule.[19] Therefore, the capital and liquidity sections of the proposed guidance remain unchanged from the 2018 FBO guidance with the exception of two minor clarifications to the capital section.

II. Overview of the Proposed Guidance

The proposed guidance begins with a description of the proposed scoping methodology and is then organized into eight substantive areas, consistent with the 2018 FBO guidance. These areas are:

1. Capital
2. Liquidity
3. Governance mechanisms
4. Operational
5. Branches
6. Group resolution plan
7. Legal entity rationalization and separability
8. Derivatives and trading activities

The proposed guidance is tailored for the Specified FBOs as compared to the U.S. GSIBs to account for differences between U.S. GSIBs and FBOs' U.S. footprints and operations. Each substantive area is important to firms in implementing their U.S. resolution strategy, as each plays a part in helping to ensure that the firms can be resolved in a rapid and orderly manner. The proposed guidance would describe the agencies' expectations for each of these areas.

The proposal is largely consistent with the 2018 FBO guidance and the 2019 domestic guidance. Accordingly, the agencies expect that the FBOs that would be Specified FBOs under the proposal have already incorporated significant aspects of the proposed guidance into their resolution planning. With respect to the 2019 domestic guidance, the proposed guidance differs in certain respects, given the circumstances under which a foreign-based covered company's U.S. resolution plan is most likely to be relevant.

As noted above, the proposal would update the PCS and DER areas of the 2018 FBO guidance to reflect the agencies' review of certain Specified FBOs' 2018 resolution plans and revisions contained in the 2019 domestic guidance. It would also make minor clarifications to certain areas of the 2018 FBO guidance in light of the 2019 revisions. In general, the proposed revisions to the guidance are intended to streamline the firms' submissions and to provide additional clarity. In addition, the proposed guidance would consolidate all guidance applicable to the Specified FBOs into a single document, which would provide the public with one source of applicable guidance to which to refer. The proposed guidance is not meant to limit firms' consideration of additional

[15] Public Law 115–174 (2018).

[16] *See* Prudential Standards for Large Bank Holding Companies, Savings and Loan Holding Companies, and Foreign Banking Organizations, 84 FR 59032 (November 1, 2019); Changes to Applicability Thresholds for Regulatory Capital and Liquidity Requirements, 84 FR 59230 (November 1, 2019).

[17] Available at *www.federalreserve.gov/newsevents/pressreleases/bcreg20181220c.htm.*

[18] *See* 84 FR 1442–43 (discussing, among other things, (i) tailoring liquidity flow assumptions; (ii) avoiding false positive resolution triggers; and (iii) other requests).

[19] *See generally* Total Loss-Absorbing Capacity, Long-Term Debt, and Clean Holding Company Requirements for Systemically Important U.S. Bank Holding Companies and Intermediate Holding Companies of Systemically Important Foreign Banking Organizations, 82 FR 8266 (January 24, 2017).

vulnerabilities or obstacles that might arise based on a firm's particular structure, operations, or resolution strategy and that should be factored into the firm's submission.

Scope of Application

The agencies are proposing to apply the guidance to FBOs whose material financial distress or failure would present the greatest potential to disrupt U.S. financial stability. Specifically, the agencies are proposing to use the method 2 calculation of the GSIB surcharge framework for determining the applicability of this proposed guidance. Accordingly, the proposed guidance would apply to FBOs that are triennial full filers [20] and whose U.S. IHCs have a method 2 GSIB score of 250 or more.[21] The agencies seek comment on all aspects of the proposed scoping methodology.

In proposing a scoping methodology, the agencies seek to provide a framework that is clear, predictable, and based on publicly reported quantitative data. Large bank holding companies, including FBOs' U.S. IHCs, already submit to the Board periodic public reports on their GSIB indicator scores. Since relevant data has been collected in comparable form for U.S. GSIBs, FBOs, and other banking organizations in the U.S., a small number of FBOs (those FBOs that currently are expected to be Specified FBOs) have had consistently high method 2 GSIB scores that persist both in comparison to U.S. GSIBs and other FBOs during the periods for which data is available.

These comparably high method 2 scores have largely been driven by a reliance on short term wholesale funding (STWF). The STWF factor indicates the potential for significant liquidity outflows and large-scale funding runs associated with STWF in times of stress. Such funding runs may complicate the ability of an FBO to undergo an orderly resolution in times of stress, generating both safety and soundness and financial stability risks. While the agencies believe that there are compelling justifications for using a standalone risk-based measure of STWF as a basis for having heightened expectations for resolution planning, the agencies also understand that a single indicator may not account for other factors that are relevant to the resolvability of an FBO.

In contrast, method 2 of the GSIB surcharge framework is designed to provide a single, comprehensive, integrated assessment of a large bank holding company's systemic footprint. Specifically, the method 2 score assesses a financial institution's asset size, interconnectedness, complexity (including over-the-counter derivatives trading), cross-jurisdictional activity, and reliance on STWF—all important factors in considering resolvability. Thus, the agencies believe that this methodology is an appropriate mechanism for determining the scope of applicability of the proposed guidance.

The agencies believe that a method 2 GSIB score of 250 or more indicates that an FBO has certain characteristics that could present barriers to a rapid and orderly resolution. For example, a firm that funds a large percentage of its assets with STWF—as noted above, a measure that suggests that a banking organization is more vulnerable to large-scale funding runs and thus increased resolvability risk—would have a method 2 GSIB score of 250 or more. Moreover, a substantial majority of U.S. GSIBs, which are the subject of heightened expectations regarding resolution planning,[22] have a GSIB method 2 score of 250 or more, suggesting the need to apply heightened resolution expectations to FBOs that present comparable resolvability challenges. In addition, the proposed guidance would only apply to FBOs with U.S. IHCs because those are the FBOs with the largest consolidated U.S. operations that are subject to resolution under the Bankruptcy Code.

The agencies are not proposing to use the tailoring rules and the accompanying framework for sorting financial institutions into certain tailoring categories, other than to confirm that a firm is a triennial full filer. Several factors for determining a financial institution's tailoring category are important in the context of resolution and the application of this proposed guidance to the Specified FBOs. However, the tailoring rules and tailoring categories were developed to determine application of a broad range of enhanced prudential standards, including the general operation of resolution plan submissions, and were not focused on determining which covered companies should be subject to more detailed resolution planning guidance in light of longer resolution planning cycles and the need for greater coordination between home and host regulators.

Question [*]: Is the proposed scope of applicability of the proposed guidance appropriate? Should the agencies adopt a different methodology for determining the scope of the proposed guidance? For example, should the proposed guidance apply to FBOs whose U.S. operations have a systemic risk profile (as assessed by the method 1 GSIB score) that is similar to the systemic risk profile of the U.S. financial institutions that are assigned to Category I under the Board's tailoring rules? Should the proposed guidance apply to FBOs that are subject to Category II standards (based on the firm's combined U.S. operations) under the Board's tailoring rules? Should the proposed guidance apply to FBOs that have exposure of a certain level (in the range of $50 to $100 billion) in one or more of the risk-based indicators identified in the Board's tailoring rules, such as nonbank assets and/or STWF? If the agencies adopt a different scope of application than what is being proposed, should the agencies also modify the content of the guidance, for example by removing certain sections of the guidance? Commenters are invited to explain in detail the basis for their positions.

Question [*]: Should the agencies outline in the final guidance their methodology and process for determining the FBOs to which the guidance should apply? Should the agencies specify in the final guidance an implementation period for any FBO that did not receive the 2018 FBO guidance, but to which the final guidance will apply? If so, should the implementation period be fixed or subject to adjustment by the agencies?

Capital: The ability to provide sufficient capital to U.S. non-branch material entities without disruption from creditors is important to ensure that such material entities can continue to provide critical services and maintain identified critical operations as the U.S. IHC is resolved. The proposal describes expectations concerning the appropriate positioning of capital and other loss-absorbing instruments (*e.g.,* debt that the parent may forgive or convert to equity) among the U.S. IHC and its subsidiaries (resolution capital adequacy and positioning or RCAP).[23] The proposal also describes expectations regarding a methodology for periodically estimating the amount of capital that may be needed to support each U.S. IHC subsidiary after the U.S. IHC's bankruptcy filing (resolution capital execution need or RCEN).

Liquidity: A firm's ability to reliably estimate and meet the liquidity needs of the U.S. IHC and its subsidiaries prior to, and in, resolution (resolution liquidity execution need or RLEN) is important to the execution of a Specified FBO's U.S. resolution strategy. Maintaining sufficient and appropriately-positioned liquidity also

[20] Currently, there are no FBOs that are triennial reduced filers and whose IHCs have method 2 scores of 250 or more. The agencies do not intend for the proposed guidance to apply to such an FBO.

[21] The Specified FBOs as of the date of this proposal would be Barclays PLC, Credit Suisse Group AG, and Deutsche Bank AG.

[22] *See* 2019 domestic guidance.

[23] The proposal also would make consistent with the 2019 domestic guidance expectations about intercompany debt.

allows the U.S. IHC subsidiaries to continue to operate while the U.S. IHC is being resolved in accordance with the firm's U.S. resolution strategy. The proposal also describes expectations concerning a methodology for measuring the stand-alone liquidity position of each U.S. non-branch material entity.

Governance Mechanisms: An adequate governance structure with triggers that identify the onset, continuation, and increase of financial stress is important to ensure that there is sufficient time to communicate and coordinate with the foreign parent regarding the provision of financial support and other key actions. The governance mechanisms section proposes expectations that firms have playbooks that describe the board and senior management actions of the U.S. non-branch material entities necessary to execute the firm's U.S. resolution strategy. In addition, the proposal describes expectations that firms have triggers that are linked to specific actions outlined in these playbooks to ensure the timely escalation of information to both U.S. IHC and foreign parent governing bodies. The proposal also describes the expectations that firms identify and analyze potential legal challenges to planned U.S. IHC support mechanisms, and any defenses and mitigants to such challenges.

Currently, certain Specified FBOs have relied on contractually binding mechanisms (''CBMs'') to ensure that sufficient capital and liquidity is timely provided to material entity subsidiaries prior to the U.S. IHC commencing a bankruptcy case. These structures are designed, in part, to mitigate potential legal challenges to the provision of such support.[24] With respect to legal challenges, the certain Specified FBOs assume, therefore, that creditors in a bankruptcy case of the U.S. IHC would exist and would bring a creditor challenge action in any bankruptcy case of the U.S. IHC.

Certain Specified FBOs have developed either (i) a secured support agreement whereby the U.S. IHC binds itself to provide pre-bankruptcy support to material entity subsidiaries, supported by perfected security interests in collateral granted by the U.S. IHC;[25] or (ii) an unsecured equity purchase arrangement under which the U.S. IHC enters into one or more agreements with a material entity subsidiary to purchase additional equity from that subsidiary prior to the U.S. IHC's bankruptcy. Under this second approach, the subsidiary would, using the funds derived from the equity investment, provide capital and liquidity support to U.S. material entities.

Neither the proposed guidance nor the Rule recommend a specific strategy for ensuring that support is timely provided to material entity subsidiaries and reducing the risk of a successful legal challenge to pre-bankruptcy resolution-related actions. The agencies continue to evaluate the efficacy of CBMs for the Specified FBOs as tools to address each of these objectives. The agencies seek comment on the benefits and costs and relative advantages and disadvantages of each CBM approach for the Specified FBOs.

Question [*]: Is each CBM approach described above effective as a potential mitigant to potential legal challenges in the case of a U.S. IHC bankruptcy? Is each effective in ensuring the provision of capital and liquidity support to material entities in periods of financial stress? What are the benefits and costs and relative advantages and disadvantages associated with each of the CBM approaches?

Question [*]: Does each of the aforementioned CBM approaches appropriately balance the certainty associated with pre-positioning capital directly at U.S. IHC subsidiaries with the flexibility provided by holding recapitalization resources at the U.S. IHC (contributable resources) to meet unanticipated losses at the U.S. IHC subsidiaries? Does each of the aforementioned CBM approaches provide sufficient confidence that appropriate levels of capital and liquidity will be timely provided to material entity subsidiaries? Does the absence of a perfected security interest under the equity purchase arrangement materially affect the likelihood that resources would be available to material entity subsidiaries under that approach? Why or why not?

Question [*]: Are there alternative CBM approaches that would provide equivalent or greater effectiveness in the provision of capital and liquidity to material entities in periods of financial stress? Should the agencies prescribe a specific CBM approach or provide additional guidance on the subject, or neither?

Question [*]: Does the existence of a CBM that follows either of the aforementioned CBM approaches have the potential to facilitate or pose a potential conflict with a Specified FBO's home country global resolution strategy? If so, are there alternative approaches that would mitigate the conflict while providing sufficient confidence that appropriate levels of capital and liquidity will be timely provided to material entity subsidiaries?

Operational: The development and maintenance of operational capabilities is important to support and enable successful execution of a firm's U.S. resolution strategy, including providing for the continuation of identified critical operations and preventing or mitigating adverse impacts on U.S. financial stability. The proposed operational capabilities include:

- Developing a framework and playbooks that consider contingency actions and alternative arrangements to be taken to maintain payment, clearing, and settlement activities and to maintain access to financial market utilities (''FMUs''), as further discussed below;
- Possessing fully developed capabilities related to managing, identifying, and valuing the collateral that is received from, and posted to, external parties and its affiliates;
- Having management information systems that readily produce key data on financial resources and positions on a U.S. legal entity basis, and that ensure data integrity and reliability; and
- Maintaining an actionable plan to ensure the continuity of all of the shared and outsourced services on which identified critical operations rely.

In addition, the proposed guidance outlines expectations that firms' plans should reflect the current state of how the early termination of qualified financial contracts could impact resolution of the firm's U.S. operations.

Branches: U.S. branches of FBOs, while legally distinct from a U.S. IHC, can play a critical role in a firm's U.S. operations. Therefore, the proposal describes expectations regarding the mapping of interconnections and interdependencies between a U.S. branch that is a material entity and other material entities, core business lines, or identified critical operations. In addition, the Specified FBOs would be expected to show how branches would continue to facilitate the firm's FMU access for identified critical operations and to meet funding needs. The proposal also outlines expectations that the Specified FBOs analyze the effects on the firm's FMU access and identified critical operations of the cessation of operations of any U.S. branch that is significant to the activities of an identified critical operation.

[24] The U.S. GSIBs previously adopted CBMs for similar purposes.

[25] FBOs operating in the United States with U.S. non-branch assets of $50 billion or more, such as the firms that would be Specified FBOs under the proposed guidance, are required to consolidate certain U.S. subsidiaries under a single, top-tier intermediate holding company. 12 CFR 252.153. In this circumstance, the U.S. IHC would be the entity that enters into a secured support agreement with its U.S. subsidiaries. Separately, some U.S.-based financial institutions have established an intermediate holding company to facilitate the flow of capital and liquidity to material entities prior to bankruptcy.

Group Resolution Plan: As noted above, the agencies recognize the preferred resolution outcome for the Specified FBOs is a successful home country resolution. U.S. operations of an FBO are often highly interconnected with the broader, global operations of the financial institution. The proposal outlines expectations for these firms to detail how resolution planning for U.S. domiciled entities or activities is integrated into the foreign-based covered company's overall resolution or other contingency planning process.

Legal Entity Rationalization and Separability: It is important that firms maintain a structure that facilitates orderly resolution. To achieve this, the proposal states that a firm should develop criteria supporting the U.S. resolution strategy and integrate them into day-to-day decision making processes. The criteria would be expected to consider the best alignment of legal entities and business lines and facilitate resolvability of U.S. operations as a firm's activities, technology, business models, or geographic footprint change over time. In addition, the proposed guidance provides that the firm should identify discrete U.S. operations that could be sold or transferred in resolution.

Derivatives and Trading Activities: It is important that a firm's derivatives and trading activities can be stabilized and de-risked during resolution without causing significant market disruption. As such, firms should have capabilities to identify and mitigate the risks associated with their U.S. derivatives and trading activities (including those activities originated from the U.S. entities (as defined below) and booked directly into a non-U.S. affiliate) and with the implementation of their preferred strategies, as further discussed below.

III. Proposed Changes From Prior Guidance

The proposed guidance contains modifications and clarifications informed by the agencies' review of the certain Specified FBOs' 2018 plans, particularly in the areas of DER and PCS. Generally, the agencies' expectations for the Specified FBOs' resolution plan submissions are consistent with their expectations for the U.S. GSIBs' resolution plan submissions, with appropriate tailoring to reflect the firms' foreign parents and their different organizational structures and operations. In addition, the proposed guidance would provide certain clarifications to address the 2019 revisions and changes within the financial industry. The following summarizes the changes relative to the 2018 FBO guidance to which the agencies are seeking comment:

Scope

The agencies have eliminated from the 2018 FBO guidance the paragraph indicating that the expectations apply to certain Specified FBOs. As indicated above, the agencies are proposing to scope application of the proposed guidance by reference to a pre-existing framework for determining systemic risk. Specifically, the proposed guidance would apply to FBOs that are triennial full filers and whose U.S. IHCs have a method 2 GSIB score of 250 or more. The agencies also are considering the appropriate implementation period for any FBO that becomes subject to the forthcoming final guidance and that was not a recipient of the 2018 FBO guidance.

Operational: Payment, Clearing, and Settlement Activities

The provision of PCS services by firms, FMUs, and agent banks is an essential component of the U.S. financial system, and maintaining the continuity of access to PCS services is important for the orderly resolution of the Specified FBOs' U.S. material entities, identified critical operations, and core business lines. Based upon the review of recent resolution plan submissions and the agencies' engagement with the firms, the agencies believe that the firms that would be Specified FBOs under the proposed guidance generally have continued to develop capabilities to identify and consider the risks associated with continuity of access to PCS services in a resolution under their U.S. resolution strategies. These capabilities are described in the firms' resolution plan methodologies and are included in playbooks for key FMUs and key agent banks.

The 2018 FBO guidance indicated that the resolution plan submission of an FBO to which the 2018 guidance applied should describe arrangements to facilitate continued access to PCS services through those FBOs' resolution. The agencies are now proposing guidance that clarifies the agencies' expectations with respect to the Specified FBOs' capabilities to maintain continued access to PCS services. First, the proposal would state that firms should develop frameworks that articulate their strategies for continued access to PCS services to focus the firms' consideration of this issue. Second, the proposed guidance would provide clarity regarding firms' playbooks for retaining access to PCS services. Finally, the proposal would distinguish between expectations related to users and providers of PCS services, to reflect the different financial and operational considerations associated with each activity. The agencies believe that the firms that would be Specified FBOs under the proposed guidance generally have methodologies and capabilities in place to address the expectations in this proposal.

Framework. The framework through which a firm maintains continued access to PCS services should incorporate the identification of key clients of a firm's U.S. operations,[26] as well as key FMUs and key agent banks for a firm's U.S. material entities, identified critical operations, and core business lines, using both quantitative [27] and qualitative criteria, and playbooks for each key FMU and key agent bank. The proposed guidance builds upon existing guidance by specifying that the framework should consider key clients of the firm's U.S. operations (which may include affiliates of the firm), key FMUs, and key agent banks.[28] The agencies note that, while the 2018 FBO guidance does not expressly suggest the identification of and development of playbooks for key agent banks, the firms that would be Specified FBOs under the proposed guidance generally considered agent bank relationships in their most recent resolution plan submissions, with each providing a playbook for at least one key agent bank. Because agent

[26] A client is an individual or entity, including affiliates of the firm, to whom the firm provides PCS services and, if credit or liquidity is offered, any related credit or liquidity offered in connection with those services. In an effort to provide additional clarity, the proposed guidance clarifies that a firm should consider any related credit or liquidity offered in connection with those services only if credit or liquidity is offered. Although this clarification is not expressly included in the 2019 domestic guidance, the agencies' expectation concerning the identification of key clients remains the same for both those U.S. banking organizations and the Specified FBOs.

[27] In identifying entities as key, examples of quantitative criteria may include: For a client, transaction volume/value, market value of exposures, assets under custody, usage of PCS services, and if credit or liquidity is offered, any extension of related intraday credit or liquidity; for an FMU, the aggregate volumes and values of all transactions processed through such FMU; and, for an agent bank, assets under custody, the value of cash and securities settled, and extensions of intraday credit.

[28] The agencies note that several footnotes have been modified from the corresponding footnotes in the 2019 domestic guidance. *Compare* 84 FR 1452 nn. 13–14 *with* V. *Payment, Clearing, and Settlement Activities* nn. 19–20. These modifications were made for clarification purposes and do not reflect a difference in expectations between Specified FBOs and the eight largest, complex U.S. banking organizations regarding the identification of key clients, key FMUs, and key agent banks.

bank relationships may replicate PCS services provided by FMUs or facilitate access to FMUs, the agencies are proposing to expressly include the development of playbooks for key agent banks.

In applying the framework, a firm would be expected to consider its role as a user or a provider of PCS services. The proposal refers to a user of PCS services as a firm that accesses the services of an FMU directly through its own membership in that FMU or indirectly through the membership of another entity, including an affiliate, that provides PCS services on an agency basis. A firm is a provider of PCS services under the proposed guidance if it provides its clients with access to an FMU or agent bank directly through the firm's membership in or relationship with that service provider, or indirectly through the firm's relationship with another entity, including a U.S. or non-U.S. affiliate or branch, that provides the firm with PCS services on an agency basis. A firm also would be a provider if it delivers PCS services to a client through the firm's own operations in the United States in a manner similar to an FMU.

The proposal provides that a firm's framework should take into account certain relevant relationships by providing a mapping of U.S. material entities, identified critical operations, core business lines, and key clients of the firm's U.S. operations to key FMUs and key agent banks. This framework would be expected to consider both direct relationships (*e.g.,* a firm's direct membership in the FMU, a firm's provision of such key clients of the firm's U.S. operations with PCS services through its own operations in the United States, or a firm's contractual relationship with an agent bank) and indirect relationships (*e.g.,* a firm indirectly accesses PCS services through its relationship with another entity, including U.S. and non-U.S. affiliates and branches, that provides the firm with PCS services on an agency basis). The agencies are not proposing to limit the framework to direct relationships and non-affiliates, since continuity of access in a resolution scenario to directly accessed and indirectly accessed PCS activities, including through affiliates, is likely to be essential to the rapid and orderly resolution of a Specified FBO.

By developing and evaluating these activities and relationships through a framework that incorporates the elements of the proposed guidance, a firm should be able to consider the issue of maintaining continuity of access to PCS services in a comprehensive manner.

Question [ ]. Is the proposed guidance sufficiently clear with respect to the following concepts: scope of PCS services, user vs. provider, and direct vs. indirect relationships? What additional clarifications or alternatives concerning the proposed framework or its elements, if any, should the agencies consider? For instance, would further examples of ways that a Specified FBO may act as provider of PCS services be useful? Should the agencies consider further distinguishing between providers based on the type of PCS service they provide?

Question [ ]. Is the proposed guidance sufficiently clear concerning expectations related to PCS services provided by a Specified FBO's U.S. material entities, whether branches or non-branches? Should the agencies consider applying different expectations for U.S. material entities based on whether they are branches or non-branch entities? If so, what should be the basis for such differing expectations, and what additional clarifications or alternatives should the agencies consider?

Playbooks for Continued Access to PCS Services. Under the proposal, it is expected that a firm would provide a playbook for each key FMU and key agent bank, whether there is a direct relationship or an indirect relationship (including indirect arrangements through any U.S. or non-U.S. affiliate or branch) between the firm and each key FMU and key agent bank. A Specified FBO also would be expected to provide a playbook for each key FMU and key agent bank that, among other things, includes financial and operational detail that would support continued access to PCS services for the firm and key clients of its U.S. operations under the firm's U.S. resolution strategy.[29]

The proposed guidance differentiates the type of information to be included in a firm's key FMU and key agent bank playbooks based on whether a firm is a user of PCS services with respect to that FMU or agent bank, a provider of PCS services with respect to that FMU or agent bank, or both. To the extent a firm is both a user and a provider of PCS services with respect to a particular FMU or agent bank, the firm would be expected to provide the described content for both users and providers of PCS services. A firm would be able to do so either in the same playbook or in separate playbooks included in its resolution plan submission.

Content related to Users of PCS Services. Each playbook for an individual key FMU or key agent bank should include a description of the firm's direct or indirect relationship as a user with the key FMU or key agent bank and an identification and mapping of PCS services to the associated U.S. material entities, identified critical operations, and core business lines that use those PCS services, as well as a discussion of the potential range of adverse actions that could be taken by that key FMU or key agent bank when the firm is in resolution under its U.S. resolution strategy.[30] Playbooks submitted as part of the 2018 resolution plan submissions generally mapped the PCS services provided to U.S. material entities, identified critical operations, and core business lines at a granular level, which enhanced the utility of these playbooks.

In discussing the potential range of adverse actions that a key FMU or key agent bank could take, each playbook would be expected to address the operational and financial impact of such actions on each U.S. material entity, identified critical operation, and core business line, and discuss contingency arrangements that the firm could initiate in response to such adverse actions by the key FMU or key agent bank. Operational impacts could include effects on governance mechanisms or resource allocation (including human resources) of the Specified FBO's U.S. operations, as well as any expected enhanced communication with key stakeholders (*e.g.,* regulators, FMUs, agent banks). Financial impacts could include those directly associated with liquidity or any additional costs incurred by the firm as a result of such adverse actions and contingency arrangements.

Content related to Providers of PCS Services. Under the proposal, a firm that is a direct or indirect provider of PCS services would be expected to identify, in its playbook for the relevant key FMU or key agent bank, key clients of its U.S. operations that rely upon PCS services provided by the firm's U.S. material entities, identified critical operations, and core business lines. Playbooks would be expected to describe the scale and way in which the firm's U.S. material entities, identified critical operations, and core business lines provide PCS services and any related credit or liquidity that may be offered by the firm in connection with such services. Similar to the content expected of users of PCS services, each playbook would be expected to include a mapping of the PCS services provided to

[29] However, the firm is not expected to incorporate a scenario in which it loses key FMU or key agent bank access into its U.S. resolution strategy or its RLEN and RCEN estimates.

[30] Examples of potential adverse actions may include increased collateral and margin requirements and enhanced reporting and monitoring.

each U.S. material entity, identified critical operation, and core business line, as well as key clients of the firm's U.S. operations. If a firm provides PCS services through its own U.S. operations, the firm would be expected to produce a playbook for the U.S. material entity that provides those services, and the playbook would focus on continuity of access for key clients of the firm's U.S. operations.

The proposal states that playbooks should discuss the potential range of contingency actions available to the firm to minimize disruption to its provision of PCS services to key clients of its U.S. operations and the financial and operational impacts of such arrangements. Contingency arrangements may include viable transfer of client activity and any related assets or any alternative arrangements that would allow key clients of the firm's U.S. operations to maintain continued access to PCS services. Each playbook also would be expected to describe the range of contingency actions that the firm may take concerning its provision of intraday credit to key clients of its U.S. operations and to provide analysis quantifying the potential liquidity that the firm could generate by taking each such action in stress and in the resolution period. To the extent a firm would not take any such actions as part of its U.S. resolution strategy, the firm would be expected to describe its reasons for not taking any contingency action.

Under the proposal, a Specified FBO should communicate the potential impacts of implementation of any identified contingency arrangements or alternatives to key clients of its U.S. operations, and playbooks should describe the firm's methodology for determining whether it should provide any additional communication to some or all such key clients of its U.S. operations (*e.g.,* due to the client's BAU usage of that access or related extensions of credit), as well as the expected timing and form of such communication. The agencies note that, in the most recent submissions of the firms that would be Specified FBOs under the proposed guidance, these firms generally addressed the issue of client communications and provided descriptions of planned or existing client communications. A firm would be expected to consider any benefit of communicating this information in multiple forms (*e.g.,* verbal or written) and at multiple time periods (*e.g.,* business as usual, stress, or some point in time in advance of taking contingency actions) in order to provide adequate notice to key clients of its U.S. operations of the action and the potential impact on the client of that action.

In making decisions concerning communications to such key clients of its U.S. operations, the proposal states that the firm also should consider tailoring communications to different subsets of clients (*e.g.,* based on levels of activity or credit usage) in form, timing, or both. Playbooks may include sample client contracts or agreements containing provisions related to the firm's provision, if any, of intraday credit or liquidity.[31] Such sample contracts or agreements may be important to the extent that the firm believes those documents sufficiently convey to clients the contingency arrangements available to the firm and the potential impacts of implementing such contingency arrangements.

Question [ ]. Are the expectations with respect to playbook content for firms that are direct or indirect users or providers (or both) of PCS services sufficiently clear? What additional clarifications, alternatives, or additional information, if any, should the agencies consider?

Question [ ]. Should the guidance indicate that providers of PCS activities are expected to consider particular contingency arrangements (e.g., methods to transfer client activity to other firms with whom the clients have relationships, alternate agent bank relationships, etc.)? Should the guidance also indicate that firms should consider particular actions they may take concerning the provision of intraday credit to affiliate and third-party clients, such as requiring pre-funding? If so, what particular actions should these firms address?

Question [ ]. Specifically for direct and indirect users of PCS activities, should the guidance indicate that firms are expected to include PCS-related liquidity sources and uses, such as client pre-funding, or specific abilities to control intraday liquidity inflows and outflows, such as throttling or prioritizing of payments? If so, what particular sources and uses should firms be expected to include?

Question [ ]. Specifically for providers of PCS services, are the agencies' expectations concerning a firm's communication to key clients of its U.S. operations (including affiliates, as applicable) of the potential impacts of implementation of identified contingency arrangements sufficiently clear? What additional clarifications, if any, should the agencies consider? Should the agencies expect the firm to communicate this information to key clients of the U.S. operations at specific times or in specific formats?

Capabilities. Similar to prior guidance, the proposal includes expectations concerning a Specified FBO's capabilities for understanding and tracking its obligations and exposures associated with PCS activities, including contractual obligations and commitments. The proposed guidance indicates that those expectations would apply with respect to the obligations and exposures associated with PCS activities for each U.S. material entity, whether a branch or non-branch, as any such entity may provide access to PCS services.

Question [ ]. Are the agencies' expectations concerning these capabilities sufficiently clear? What additional clarifications, if any, should the agencies consider?

Operational: Qualified Financial Contracts

The 2018 FBO guidance indicated that the FBOs that were the subject of the 2018 FBO guidance could discuss in their resolution plan submissions the deployment and impact of certain International Swaps and Derivatives Association (''ISDA'') protocol developments on their resolution plans. The Specified FBOs may use those ISDA protocols to comply with the qualified financial contract stay rules of the Board, Office of the Comptroller of the Currency, and FDIC (''QFC Stay Rules'').[32] As firms may comply with the QFC Stay Rules by amending contracts directly, if desired, rather than using the ISDA protocols, and because those ISDA protocols are final and open for adherence, the agencies are proposing to remove language in the guidance related to these developments. The agencies propose to retain an expectation that firms' plans reflect the current state of how the early termination of qualified financial contracts could impact the resolution of the firm's U.S. operations.

Legal Entity Rationalization and Separability

The separability section of the proposed guidance has been updated to provide additional specificity on actionability and generally aligns with the agencies' expectations as described in the 2019 domestic guidance. A firm's separability options should be actionable and should identify impediments and related mitigation strategies in advance. The proposed guidance notes that the Specified FBOs should consider potential consequences to U.S. financial stability of executing each separability option, while also noting that detail and analysis should be

[31] If these sample client contracts or agreements are included separately as part of the firm's resolution plan submission, they may be incorporated into the playbook by reference.

[32] 12 CFR part 47 (Office of the Comptroller of the Currency); 12 CFR part 252, subpart I (Board); and 12 CFR part 382 (FDIC).

commensurate with each Specified FBO's U.S. risk profile and operations.

The proposed guidance has also been updated to reflect revised expectations around maintaining active virtual data rooms for separability options that involve a sale of U.S. operations or businesses (''objects of sale''). Consistent with expectations described in the 2019 domestic guidance, firms would be expected to have the capability to populate a data room with information pertinent to a potential divestiture in a timely manner, rather than to maintain an active data room. The agencies would expect to test this capability by asking firms to produce selected sale-related materials within a certain timeframe as part of future resolution plan reviews.

Derivatives and Trading Activities

The size, scope, complexity, and potential for opacity of a Specified FBO's U.S. derivatives and trading activities [33] may present significant risk to the resolvability of the firm's U.S. entities.[34] Based on the agencies' review of these firms' most recent resolution plan submissions,[35] the agencies have observed that the firms that would be Specified FBOs under the proposed guidance are increasingly booking U.S. derivatives and trading activities that originate from U.S. entities [36] into non-U.S. affiliates. As a result, the booking of U.S. derivatives and trading activities regularly occurs across jurisdictions and creates interconnections and interdependencies among and between the U.S. entities and non-U.S. affiliates of firms that would be Specified FBOs under the proposed guidance.[37] It can be difficult for the agencies to evaluate a firm's U.S. derivatives and trading activities, and related risks to U.S. financial stability during the execution of the firm's U.S. resolution strategy, without considering these activities on a broader basis (*e.g.,* a cross-jurisdictional, business line basis). This is particularly true for the firm's U.S. derivatives and trading activities originated from U.S. entities that are booked directly into a non-U.S. affiliate. Greater transparency into these activities is important because the U.S. entities have ongoing responsibilities for U.S. derivatives and trading activities originated from U.S. entities such as management of client relationships, transaction settlement, management of risk limits, and maintenance of access to U.S. FMUs, in the period leading-up to and during execution of the U.S. resolution strategy.

Uncertainty about the execution risk, allocation of losses, and impact on clients and counterparties of the U.S. entities could contribute to a loss of confidence in the firm's U.S. resolution strategy. To facilitate an orderly resolution of its U.S. entities, a Specified FBO should be able to demonstrate the ability to monitor and manage its U.S. derivatives and trading activities in the period leading-up to and during execution of the U.S. resolution strategy without risk of a serious adverse effect on U.S. financial stability. The firms that would be Specified FBOs under the proposed guidance have been developing certain capabilities to identify and mitigate the risks associated with their U.S. derivatives and trading activities and with the implementation of their U.S. resolution strategies. These capabilities seek to facilitate a firm's planning, preparedness, and execution of an orderly resolution of its U.S. entities. Notably, they also may facilitate a home-country led strategy.[38]

The proposed guidance would clarify the agencies' expectations with respect to such capabilities and a firm's analysis of its U.S. resolution strategy. The proposed guidance also would eliminate the expectations of the 2018 FBO guidance that a firm's U.S. resolution plan include separate passive and active wind-down scenario analyses, the agency-specified data templates, and rating agency playbooks, which is consistent with the 2019 domestic guidance. In addition, relative to the 2019 domestic guidance, the proposed guidance would modify certain expectations for the Specified FBOs to reflect better the structures and business activities of the firms that would be Specified FBOs under the proposed guidance, including the size and complexity of their U.S. derivatives and trading activities and the associated risks to the orderly resolution of their U.S. entities. In particular, the proposed modifications would change the scope of activities covered by the *Booking Practices* subsection from derivatives portfolios [39] to U.S. derivatives and trading activities.[40] The proposal would also replace the *Inter-Affiliate Risk Monitoring and Controls* subsection with a new *U.S. Activities Monitoring* subsection to place an appropriate focus on the firm's ability to provide timely transparency into the U.S. derivatives and trading activities, regardless of where the transactions are booked. Finally, in consideration of the relatively smaller size and less complex nature of the derivatives positions booked directly into U.S. IHC subsidiaries of the firms that would be Specified FBOs under the proposed guidance, the proposal would eliminate the ''*ease of exit*'' position analysis, ''*application of exit cost methodology,*'' and ''*analysis of operational capacity*'' subsections.[41] As described in more detail below, the proposed derivatives and trading activities guidance is organized into five subsections.

Booking practices. To minimize uncertainty, complexity, and opacity around cross-jurisdictional booking practices that could frustrate a firm's resolution preparedness, a firm's resolution capabilities should include booking practices for its U.S. derivatives

[33] ''U.S. derivatives and trading activities'', means all derivatives and trading activities that are: (1) Related to a firm's identified critical operations or core business lines, including any such activities booked directly into a non-U.S. affiliate; (2) conducted on behalf of the firm, its clients, or counterparties that are originated from, booked into, traded through, or otherwise conducted (in whole or in material part) in a U.S. entity (as defined below); or (3) both of the foregoing. A firm should identify its U.S. derivatives and trading activities pursuant to a methodology and justify the methodology used.

[34] ''U.S. entities'' means U.S. IHC subsidiaries and material entity branches.

[35] Each of the 2018 resolution plans of the firms that would be Specified FBOs under the proposed guidance identifies certain U.S. derivatives and trading activities (including U.S. prime brokerage services) as an identified critical operation or core business line.

[36] Activities ''originated'' from U.S. entities are those activities transacted or arranged by, or on behalf of those U.S. entities and their clients and counterparties, including any such activity for which the U.S. entity is compensated (directly or indirectly) by a non-U.S. affiliate. These activities also include, for example, those that are sourced or executed through personnel employed by or acting on behalf a U.S. entity. The agencies would expect that a U.S. entity that is significant to the origination of activities for an identified critical operation or core business line would be designated as a U.S. material entity.

[37] The Rule requires a Specified FBO to identify, describe in detail, and map to the legal entity the interconnections and interdependencies among the U.S. subsidiaries, branches and agencies, and between those entities and the identified critical operations and core business lines of the Specified FBO, and any foreign-based affiliate. *See* 12 CFR 243.5(a)(2)(i); 12 CFR 381.5(a)(2)(i).

[38] An SPOE strategy has been identified as the preferred group resolution strategy for each of the firms that would be Specified FBOs under the proposed guidance. *See supra* Objectives of the Resolution Planning Process.

[39] A firm's derivatives portfolios include its derivatives positions and linked non-derivatives trading positions.

[40] This modification would extend the scope of the booking practices beyond derivatives portfolios to include, for example, securities financing transactions originated from the firm's U.S. prime brokerage business on behalf of a U.S. client but booked directly into a non-U.S. affiliate.

[41] While this modification would eliminate the more detailed expectations in subsections on ''*application of exit cost methodology*'' and ''*analysis of operational capacity,*'' similar considerations specific to the analysis of a firm's derivatives strategy are still captured within the ''*derivatives stabilization and de-risking strategy*'' section.

and trading activities that are commensurate with the size, scope, and complexity of a firm's U.S. derivatives and trading activities. A firm should have booking practices that provide timely and up-to-date information regarding the structure of and risks associated with the management of its U.S. derivatives and trading activities. In addition to providing transparency with respect to those positions booked into U.S. entities, the booking framework should provide transparency with respect to U.S. derivatives and trading activities booked directly to non-U.S. affiliates. As noted above, due to the cross-border nature of these activities, it can be difficult to evaluate the activities and the related risk in the period leading-up to and during the execution of the firm's U.S. resolution strategy without considering certain activities on a cross-jurisdictional, business line basis.[42] Therefore, the proposed guidance would clarify the capabilities a firm is expected to have related to its booking practices, including descriptions of its booking model framework and demonstrations of its ability to identify, assess, and report on each U.S. entity that originates or otherwise conducts (in whole or in material part) any significant aspect of the firm's U.S. derivatives or trading activities.

U.S. activities monitoring. The booking, funding, and risk transfer arrangements[43] underlying a firm's U.S. derivatives and trading activities create interconnections and interdependencies among and between a firm's U.S. entities and their non-U.S. affiliates that, if disrupted, could affect materially the funding or operations of the U.S. entities that conduct the U.S. derivative and trading activities or their clients and counterparties. As noted above, the U.S. entities may maintain ongoing responsibilities for U.S. derivatives and trading activities originated from U.S. entities in the period leading-up to and during the execution of the firm's U.S. resolution strategy and a lack of transparency into how these activities are managed could create uncertainty that may impact negatively the orderly resolution of the firm's U.S. entities.

For example, through their derivatives and trading activities, the firms that would be Specified FBOs under the proposed guidance provide trade execution, hedging, securities financing, custody, clearing, and related services for banking firms, hedge funds and other institutional clients and counterparties. Many of these clients and counterparties rely on the firm's execution and financing services to support their participation in U.S. financial markets. The derivatives and trading activities that are originated from the firm's U.S. entities, and then booked to the firm's non-U.S. affiliates, create operational and financial connectivity with the firm's non-U.S. entities; as a client's assets, positions and balances can be booked to or utilized by numerous U.S. and non-U.S. affiliates. In resolution, the U.S. entities may continue to have responsibilities for managing U.S. client relationships and facilitating the unwind of client positions, the settlement of client liabilities, and the transfer of client accounts, regardless of the entity within the global firm to which those positions or assets have been booked.

The rapid withdrawal of client account balances, may have negative impacts (*e.g.,* loss of internalization) on the funding or operations of the firm and its affiliates. Yet, the untimely transfer or other prolonged disruptions in the clients' ability to execute transactions may have negative impacts to those clients or the U.S. financial markets in which they participate. Therefore, the proposal clarifies the agencies' expectations that a firm address this risk by being able to provide timely transparency into the management of its U.S. derivatives and trading activities, including those originated from U.S. entities and booked directly into non-U.S. affiliates. A firm also should be able to assess the potential impact on the firm's clients and counterparties engaged in U.S. derivatives and trading activities and related risk transfer arrangements among and between the U.S. entities and non-U.S. affiliates.

Prime brokerage customer account transfers. The rapid withdrawal from a firm by U.S. prime brokerage clients can contribute to a disorderly resolution. The firm's resolution plan should address the risk that during a resolution, the firm's U.S. prime brokerage clients may seek to withdraw or transfer customer accounts balances in rates significantly higher than normal business conditions. The proposed guidance confirms that a firm should have the capabilities to facilitate the orderly transfer of U.S. prime brokerage account balances[44] to peer prime brokers and describes the agencies' related expectations in greater detail. In particular, the proposed guidance clarifies that a firm's U.S. resolution plan should describe and demonstrate its ability to segment and analyze the quality and composition of such account balances.

Portfolio segmentation. The ability to identify quickly and reliably problematic derivatives positions and portfolios is critical to minimizing uncertainty and estimating resource needs to enable an orderly resolution of the firm's U.S. entities. The proposal confirms that a firm should have the capabilities to produce analyses that reflect granular portfolio segmentation, taking into account trade-level characteristics and at an entity level, for any derivatives portfolio of a U.S. entity.

Derivatives stabilization and de-risking strategy. A key risk to the orderly resolution of the firm's U.S. entities is a volatile and risky derivatives portfolio. In the event of material financial distress or failure, the resolvability risks related to a firm's U.S. derivatives and trading activities could be a key obstacle to the firm's rapid and orderly resolution of any U.S. IHC subsidiary with a derivatives portfolio. The firms' resolution plans should address this obstacle. The proposed guidance confirms that a firm's plan should provide a detailed analysis of its strategy to stabilize and de-risk any derivatives portfolio of any U.S. IHC subsidiary that continues to operate after the U.S. IHC enters into a U.S. bankruptcy proceeding (U.S. derivatives strategy) and provides additional detail regarding the agencies' expectations.[45]

[42] The scope of the proposed guidance is larger and broader for a Specified FBO relative to the 2019 domestic guidance and includes, for example, account balances and securities financing transactions related to prime brokerage services and other derivatives trading businesses because a Specified FBO's U.S resolution plan may not provide a full (global) legal entity view of its U.S. derivatives and trading activities originated from U.S. entities. In order to understand better the potential risk in resolution (*e.g.,* potential impacts on the stability of U.S. financial markets), the agencies need to understand the material interconnections and interdependencies among and between the firm's U.S. entities and its non-U.S. affiliates that are created through its U.S. derivatives and trading activities, including those positions originated from the U.S. entities and booked directly into a non-U.S. affiliate.

[43] Risk transfer arrangements often apply to a range of services and activities (*e.g.,* trading, management, sales, infrastructure) that are provided, conducted, or used by U.S. entities. The relevant services and activities include those conducted in whole or in material part in the United States. In some instances, risk transfer arrangements may account for a material portion of the U.S. IHC's revenue. Disruption to these risk transfer arrangements could result in unexpected losses to or disruption of U.S. operations.

[44] ''U.S. prime brokerage account'' or ''U.S. prime brokerage account balances'' should include the account positions and balances of a client of the U.S. prime brokerage business, regardless of where the positions or balances are booked.

[45] Subject to certain constraints, a firm's U.S. derivatives strategy may take the form of a going concern strategy, an accelerated de-risking strategy (*e.g.,* active wind-down), or an alternative, third strategy so long as the firm's U.S. resolution plan supports adequately the firm's ability to execute the chosen strategy.

In particular, the proposed guidance clarifies that a firm should incorporate into its U.S. derivatives strategy assumptions consistent with a lack of access to the bilateral OTC derivatives market at the start of its resolution period. The proposed guidance also confirms and clarifies expectations related to other elements that should be addressed in the firm's analysis of its U.S. derivatives strategy, including the incorporation of resource needs into its RLEN and RCEN estimates (forecasts of resource needs); an analysis of any potential derivatives portfolio remaining after the resolution period (potential residual derivatives portfolio); a method to apply sensitivity analyses to the key drivers of the derivatives-related costs and liquidity flows under its U.S. derivatives strategy (sensitivity analysis); and the impact from the assumed failure of a U.S. IHC subsidiary with a derivatives portfolio (non-surviving entity analysis).

Question [ ]: Should the proposed guidance incorporate a set of criteria explaining the circumstances under which the expectations related to derivatives and trading activities apply to firms that would be Specified FBOs under the proposed guidance? If so, what criteria would be the most relevant indicators of a derivatives and trading portfolio that may pose risks to the orderly resolution of a firm? For example, should the agencies consider some or all of the following indicia: being a foreign GSIB subject to U.S. Internal TLAC requirements, having an identified critical operation or a core business line related to U.S. derivatives and trading activities, or other indicia?

Question [ ]: Is the proposed guidance sufficiently clear with respect to the following concepts: U.S. derivatives and trading activities, activities originated from U.S. entities, risk transfer arrangements, and U.S. prime brokerage accounts? What additional clarifications or alternatives concerning the proposed derivatives and trading practices framework or its elements, if any, should the agencies consider?

Question [ ]: Is the proposed guidance sufficiently clear concerning the scope of expectations related to the Booking Practices and U.S. Activities Monitoring subsections? Should the agencies consider applying a different scope of expectations for these subsections? For instance, should the scope of these subsections only include U.S. derivatives activities, instead of both U.S. derivatives and trading activities (e.g., securities financing transactions)? If so, what should be the basis for such differing expectations, and what additional clarifications or alternatives should the agencies consider?

Question [ ]: Is the proposed guidance sufficiently clear concerning the scope of expectations related to the Prime Brokerage Customer Account Transfers subsection? Should the agencies consider applying a different scope of expectations for this subsection? For instance, should the scope of this subsection only apply to account positions and balances that are booked into U.S. IHC subsidiaries? If so, what should be the basis for such differing expectations, and what additional clarifications or alternatives should the agencies consider?

Question [ ]: Is the proposed guidance sufficiently clear concerning the scope of expectations related to the Portfolio Segmentation subsection? Should the agencies consider applying a different scope of expectations for this subsection? For instance, should the scope of this subsection only apply to U.S. IHC subsidiaries with a derivatives portfolio, instead of both U.S. IHC subsidiaries and U.S. material entity branches with a derivatives portfolio? If so, what should be the basis for such differing expectations, and what additional clarifications or alternatives should the agencies consider?

Format and Structure of Plans

This section has been added to the proposed guidance as part of the consolidation of the prior guidance with the proposed guidance. The proposed guidance states the agencies' preferred presentation regarding the format, assumptions, and structure of resolution plans. Plans should contain an executive summary, a narrative of the firm's resolution strategy, relevant technical appendices, and a public section as detailed in the Rule. The proposed format, structure, and assumptions are similar to those incorporated into the 2019 domestic guidance.

Question [*]: Do the topics in the proposed guidance discussed above represent the key vulnerabilities of the Specified FBOs in resolution? If not, what key vulnerabilities are not captured?

Question [*]: The proposal incorporates portions of, and is generally aligned with, the 2018 FBO guidance and components of the 2019 domestic guidance. Are there any components of the proposal that should be augmented or removed? *If so, which provisions? Are there any elements of the proposed guidance that are not relevant to the Specified FBOs? If such is the case, commenters are invited to explain in detail and provide evidence to support their views.*

Consolidation of Prior Guidance

In addition to the 2018 FBO guidance, the agencies have also issued and provided to certain FBOs: The *Guidance for 2013 § 165(d) Annual Resolution Plan Submissions by Foreign-Based Covered Companies that Submitted Initial Resolution Plans in 2012;* firm-specific feedback letters issued in 2014 and 2018; the February 2015 staff communication regarding the 2016 plan submissions; and the July 2017 *Resolution Plan Frequently Asked Questions* (taken together, ''Prior Guidance''). The agencies are proposing to consolidate all Prior Guidance into a single document, which would provide the public with one source of applicable guidance to which to refer. Under the proposal, Prior Guidance would be superseded to the extent not incorporated in or appended to the guidance.

Question [*]: The proposed guidance reflects consolidation of all applicable Prior Guidance. Should the Agencies consolidate all applicable Prior Guidance? If so, are there additional aspects of Prior Guidance that warrant inclusion, additional clarification, or modification?

Identified Critical Operations

In the 2019 revisions, the agencies adopted a new definition, ''identified critical operations,'' to clarify that critical operations can be identified by either a covered company or jointly identified by the agencies.[46] The agencies are proposing to incorporate this new definition throughout the proposed guidance where, previously, the term ''critical operations'' was used. This modification does not change the substance of the proposed guidance.

IV. Paperwork Reduction Act

Certain provisions of the proposal contain ''collection of information'' requirements within the meaning of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521) (''PRA''). In accordance with the requirements of the PRA, the agencies may not conduct or sponsor, and a respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (''OMB'') control number.

As detailed above, the proposal is largely consistent with the 2018 FBO guidance. The proposed changes are mainly in the areas of derivatives and trading activities and payment, clearing and settlement activities. After considering these proposed changes and any potential PRA impacts, the agencies have determined that, generally, the proposal would not revise the reporting requirements that have been previously cleared by the OMB under the Board's control number (7100–0346) and under the FDIC's control number (3064–0210). However, as a result of the proposed guidance, for purposes of the PRA analysis, one covered company currently categorized in the 2019 revisions as a triennial full complex foreign filer would be re-categorized as a triennial full foreign filer. Because of the nature of the split in burden between the Board and the FDIC, the FDIC will make an adjustment to its PRA clearance (3064–0210) to account

[46] 84 FR 59210; 59218.

for the one-firm shift in category. The proposal would not add any recordkeeping or third-party disclosure requirements under the PRA. The agencies invite public comment on this assessment.

Comments are invited on:

(a) Whether the collections of information are necessary for the proper performance of the Board's and the FDIC's functions, including whether the information has practical utility;

(b) The accuracy of the estimate of the burden of the information collections, including the validity of the methodology and assumptions used;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of information collections on respondents, including through the use of automated collection techniques or other forms of information technology;

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information; and

(f) Burden estimates for preparation of the waiver request and the calculation of any associated reduction in burden.

V. Text of the Proposed Guidance

Guidance for Resolution Plan Submissions of Certain Foreign-Based Covered Companies

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a. Capabilities
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Guidance for Resolution Plan Submissions of Certain Foreign-based Covered Companies

I. Introduction

Section 165(d) of the Dodd-Frank Wall Street Reform and Consumer Protection Act (12 U.S.C. 5365(d)) requires certain foreign-based financial companies to report periodically to the Board of Governors of the Federal Reserve System (the Federal Reserve or Board) and the Federal Deposit Insurance Corporation (the FDIC) (together the Agencies) their plans for rapid and orderly resolution in the event of material financial distress or failure. On November 1, 2011, the Agencies promulgated a joint rule implementing the provisions of Section 165(d).[1] Subsequently, in November 2019, the Agencies finalized amendments to the joint rule addressing amendments to the Dodd-Frank Act made by the Economic Growth, Regulatory Relief, and Consumer Protection Act and improving certain aspects of the joint rule based on the Agencies' experience implementing the joint rule since its adoption.[2] Financial companies meeting criteria set out in the Rule must file a resolution plan (Plan) according to the schedule specified in the Rule.

This document is intended to provide guidance to certain foreign banking organizations regarding development of their respective U.S. resolution strategies (Specified FBOs or firms). Specifically, the guidance applies to FBOs that are triennial full filers [3] and whose intermediate holding companies required to be formed pursuant to 12 CFR 252 have a method 2 GSIB score of 250 or more. The document is intended to assist these firms in further developing their U.S. resolution strategies. The document does not have the force and effect of law. Rather, it describes the Agencies' expectations and priorities regarding these firms' Plans and the Agencies' general views regarding specific areas where additional detail should be provided and where certain capabilities or optionality should be developed and maintained to demonstrate that each firm has considered fully, and is able to mitigate, obstacles to the successful implementation of their U.S. resolution strategy.[4]

The Agencies are providing guidance to the Specified FBOs to assist their further development of a resolution plan for their U.S. operations for their July 1, 2021 and subsequent resolution plan submissions.[5] The guidance for Specified FBOs differs in certain respects from the guidance issued in December 2018 for certain U.S.-based covered companies given the circumstances under which a U.S. resolution plan is most likely to be relevant. The U.S. resolution plan for a Specified FBO would address a scenario where the U.S. operations experience material financial distress and the foreign parent is unable or unwilling to provide sufficient financial support for the continuation of U.S. operations, and at least the top tier U.S. Intermediate Holding Company (U.S. IHC) files for Chapter 11 bankruptcy. Under such a scenario, the Plan should provide for the rapid and orderly resolution of the Specified FBO's U.S. material entities and operations.

In general, this document is organized around a number of key vulnerabilities in resolution (*e.g.,* capital; liquidity; governance mechanisms; operational; legal entity rationalization and separability; and derivatives and trading activities) that apply across resolution plans. Additional vulnerabilities or obstacles may arise based on a firm's particular structure, operations, or resolution strategy. Each firm is expected to satisfactorily address these vulnerabilities in its Plan—*e.g.,* by developing sensitivity analysis for certain underlying assumptions, enhancing capabilities, providing detailed analysis, or increasing optionality development, as indicated below.

The Agencies will review the Plan to determine if it satisfactorily addresses

[1] 76 FR 67323 (November 1, 2011), codified at 12 CFR parts 243 and 381.

[2] Resolution Plans Required, 84 FR 59194 (November 1, 2019). The amendments became effective December 31, 2019. ''Rule'' means the joint rule as amended in 2019. Capitalized terms not defined herein have the meanings set forth in the Rule.

[3] *See* 12 CFR 243.4(b)(1); 12 CFR 381.4(b)(1).

[4] This guidance consolidates the *Guidance for 2018 § 165(d) Annual Resolution Plan Submissions by Foreign-Based Covered Companies that Submitted Resolution Plans in July 2015*; the July 2017 *Resolution Plan Frequently Asked Questions*; feedback letters issued to certain foreign-based Covered Companies in December 2018 and in August 2014; the communications the Agencies made to certain foreign-based Covered Companies in February 2015; and the *Guidance for 2013 § 165(d) Annual Resolution Plan Submissions by Foreign-Based Covered Companies that Submitted Initial Resolution Plans in 2012* (taken together, prior guidance). To the extent not incorporated in or appended to this guidance, prior guidance is superseded.

[5] Consistent with prior communications to the firms that would be Specified FBOs under the proposed guidance, they are required to submit resolution plans on or before July 1, 2020 that may be limited to describing changes that those FBOs have made to their July 2018 resolution plans to address shortcomings identified in those resolution plans.

key potential vulnerabilities, including those detailed below. If the Agencies jointly decide that these matters are not satisfactorily addressed in the Plan, the Agencies may determine jointly that the Plan is not credible or would not facilitate an orderly resolution under the U.S. Bankruptcy Code.

II. Capital

Resolution Capital Adequacy and Positioning (RCAP): In order to help ensure that a firm's U.S. non-branch material entities [6] could be resolved in an orderly manner, the firm's U.S. IHC should have an adequate amount of loss-absorbing capacity to execute its U.S. resolution strategy. Thus, a firm's U.S. IHC should hold total loss-absorbing capital, as well as long-term debt, to help ensure that the firm has adequate capacity to meet that need at a consolidated level of the U.S. IHC (IHC TLAC).[7]

A firm's IHC TLAC should be complemented by appropriate positioning of that loss-absorbing capacity between the U.S. IHC and the U.S. IHC subsidiaries. The positioning of a firm's IHC TLAC should balance the certainty associated with pre-positioning internal TLAC directly at U.S. IHC subsidiaries with the flexibility provided by holding recapitalization resources at the U.S. IHC (contributable resources) to meet unanticipated losses at the U.S. IHC subsidiaries. That balance should take account of both pre-positioning at U.S. IHC subsidiaries and holding resources at the U.S. IHC, and the obstacles associated with each. The firm should not rely exclusively on either full pre-positioning or U.S. IHC contributable resources to execute its U.S. resolution strategy, unless it has only one U.S. IHC subsidiary that is an operating subsidiary. The plan should describe the positioning of internal TLAC among the U.S. IHC and the U.S. IHC subsidiaries, along with analysis supporting such positioning.

Finally, to the extent that pre-positioned internal TLAC at a U.S. IHC subsidiary is in the form of intercompany debt and there are one or more entities between the lender and the borrower, the firm should structure the instruments so as to ensure that the U.S. IHC subsidiary can be recapitalized.

Resolution Capital Execution Need (RCEN): To the extent required by the firm's U.S. resolution strategy, U.S. non-branch material entities need to be recapitalized to a level that allows for an orderly resolution. The firm should have a methodology for periodically estimating the amount of capital that may be needed to support each U.S. IHC subsidiary after the U.S. IHC bankruptcy filing (RCEN). The firm's positioning of IHC TLAC should be able to support the RCEN estimates.

The firm's RCEN methodology should use conservative forecasts for losses and risk-weighted assets and incorporate estimates of potential additional capital needs through the resolution period,[8] consistent with the firm's resolution strategy for its U.S. operations. The methodology is not required to produce aggregate losses that are greater than the amount of IHC TLAC that would be required for the firm under the Board's final rule.[9] The RCEN methodology should be calibrated such that recapitalized U.S. IHC subsidiaries have sufficient capital to maintain market confidence as required under the U.S resolution strategy. Capital levels should meet or exceed all applicable regulatory capital requirements for ''well-capitalized'' status and meet estimated additional capital needs throughout resolution. U.S. IHC subsidiaries that are not subject to capital requirements may be considered sufficiently recapitalized when they have achieved capital levels typically required to obtain an investment-grade credit rating or, if the entity is not rated, an equivalent level of financial soundness. Finally, the methodology should be independently reviewed, consistent with the firm's corporate governance processes and controls for the use of models and methodologies.

III. Liquidity

The firm should have the liquidity capabilities necessary to execute its U.S resolution strategy, including those described below. For resolution purposes, these capabilities should include having an appropriate model and process for estimating and maintaining sufficient liquidity at—or readily available from the U.S. IHC to—U.S. IHC subsidiaries, and a methodology for estimating the liquidity needed to successfully execute the U.S. resolution strategy, as described below.

Capabilities: A firm is expected to have a comprehensive understanding of funding sources, uses, and risks at material entities and identified critical operations, including how funding sources may be affected under stress. For example, a firm should have and describe its capabilities to:

- Evaluate the funding requirements necessary to perform identified critical operations, including shared and outsourced services and access to financial market utilities (FMUs); [10]
- Monitor liquidity reserves and relevant custodial arrangements by jurisdiction and material entity; [11]
- Routinely test funding and liquidity outflows and inflows for U.S. non-branch material entities at the legal entity level under a range of adverse stress scenarios, taking into account the effect on intra-day, overnight, and term funding flows between affiliates and across jurisdictions;
- Assess existing and potential restrictions on the transfer of liquidity between U.S. non-branch material entities; [12] and
- Develop contingency strategies to maintain funding for U.S. non-branch material entities and identified critical operations in the event of a disruption in the Specified FBO's current funding model.[13]

Resolution Liquidity Adequacy and Positioning (RLAP): With respect to RLAP, the firm should be able to measure the stand-alone liquidity position of each U.S. non-branch material entity—*i.e.,* the high-quality liquid assets (HQLA) at the U.S. non-branch material entity less net outflows to third parties and affiliates—and ensure that liquidity is readily available to meet any deficits. The RLAP model should cover a period of at least 30 days and reflect the idiosyncratic liquidity profile of the U.S. IHC and risk of each U.S. IHC subsidiary. The model should balance the reduction in frictions associated with holding liquidity directly at the U.S. IHC subsidiary with the flexibility provided by holding HQLA at the U.S. IHC or at a U.S. IHC subsidiary available to meet unanticipated outflows at other U.S. IHC subsidiaries.[14] The firm should not

[6] The terms ''material entities,'' ''identified critical operations,'' and ''core business lines'' have the same meaning as in the Rule. The term ''U.S. material entity'' means any subsidiary, branch, or agency that is a material entity and is domiciled in the United States. The term ''U.S. non-branch material entity'' means a material entity organized or incorporated in the U.S. including, in all cases, the U.S. IHC. The term ''U.S. IHC subsidiaries'' means all U.S. non-branch material entities other than the U.S. IHC.

[7] Total Loss-Absorbing Capacity, Long-Term Debt, and Clean Holding Company Requirements for Systemically Important U.S. Bank Holding Companies and Intermediate Holding Companies of Systemically Important Foreign Banking Organizations, 82 FR 8266 (January 24, 2017).

[8] The resolution period begins immediately after the U.S. IHC bankruptcy filing and extends through the completion of the U.S. resolution strategy.

[9] 82 FR 8266 (January 24, 2017).

[10] 12 CFR 252.156(g)(3).

[11] 12 CFR 252.156(g)(2).

[12] Id.

[13] 12 CFR 252.156(e).

[14] To the extent HQLA is held at the U.S. IHC or at a U.S. IHC subsidiary, the model must consider whether such funds are freely available. To be

Continued

rely exclusively on either full pre-positioning or U.S. IHC contributable resources to execute its U.S. resolution strategy, unless it has only one U.S. IHC subsidiary that is an operating subsidiary.

The model [15] should ensure that on a consolidated basis the U.S. IHC holds sufficient HQLA to cover net liquidity outflows of the U.S. non-branch material entities. The model should also measure the stand-alone net liquidity positions of each U.S. non-branch material entity. The stand-alone net liquidity position of each U.S. non-branch material entity (HQLA less net outflows) should be measured using the firm's internal liquidity stress test assumptions and should treat inter-affiliate exposures in the same manner as third-party exposures. For example, an overnight unsecured exposure to a non-U.S. affiliate should be assumed to mature. Finally, the firm should not assume that a net liquidity surplus at any U.S. IHC subsidiary that is a depository institution could be moved to meet net liquidity deficits at an affiliate, or to augment U.S. IHC resources, consistent with Regulation W.

Additionally, the RLAP methodology should take into account for each of the U.S. IHC, U.S. IHC subsidiaries, and any branch that is a material entity (A) the daily contractual mismatches between their respective inflows and outflows; (B) their respective daily flows from movement of cash and collateral for all inter-affiliate transactions; and (C) their respective daily stressed liquidity flows and trapped liquidity as a result of actions taken by clients, counterparties, key FMUs, and foreign supervisors, among others.

In calculating its RLAP estimate, the U.S. IHC should calculate its liquidity position with respect to its foreign parent, branches and agencies, and other affiliates (together, affiliates) separately from its liquidity position with respect to third parties, and should not offset inflows from affiliated parties against outflows to external parties. In addition, a U.S. IHC should use cash-flow sources from its affiliates to offset cash-flow needs of its affiliates only to the extent that the term of the cash-flow source from its affiliates is the same as, or shorter than, the term of the cash-flow need of its affiliates.[16]

Resolution Liquidity Execution Need (RLEN): The firm should have a methodology for estimating the liquidity needed after the U.S. IHC's bankruptcy filing to stabilize any surviving U.S. IHC subsidiaries and to allow those entities to operate post-filing, in accordance with the U.S. strategy.

The firm's RLEN methodology should:

(A) Estimate the minimum operating liquidity (MOL) needed at each U.S. IHC subsidiary to ensure those entities could continue to operate, to the extent relied upon in the U.S. resolution strategy, after implementation of the U.S. resolution strategy and/or to support a wind-down strategy;

(B) Provide daily cash flow forecasts by U.S. IHC subsidiary to support estimation of peak funding needs to stabilize each entity under resolution;

(C) Provide a comprehensive breakout of all inter-affiliate transactions and arrangements that could impact the MOL or peak funding needs estimates for the U.S. IHC subsidiaries; and

(D) Estimate the minimum amount of liquidity required at each U.S. IHC subsidiary to meet the MOL and peak needs noted above, which would inform the provision of financial resources from the foreign parent to the U.S. IHC, or if the foreign parent is unable or unwilling to provide such financial support, any preparatory resolution-related actions.

The MOL estimates should capture U.S. IHC subsidiaries' intraday liquidity requirements, operating expenses, working capital needs, and inter-affiliate funding frictions to ensure that U.S. IHC subsidiaries could operate without disruption during the resolution.

The peak funding needs estimates should be projected for each U.S. IHC subsidiary and cover the length of time the firm expects it would take to stabilize that U.S. IHC subsidiary. Inter-affiliate funding frictions should be taken into account in the estimation process.

The firm's forecasts of MOL and peak funding needs should ensure that U.S. IHC subsidiaries could operate through resolution consistent with regulatory requirements, market expectations, and the firm's post-failure strategy. These forecasts should inform the RLEN estimate, *i.e.,* the minimum amount of HQLA required to facilitate the execution of the firm's strategy for the U.S. IHC subsidiaries.

For nonsurviving U.S. IHC subsidiaries, the firm should provide analysis and an explanation of how the material entity's resolution could be accomplished within a reasonable period of time and in a manner that substantially mitigates the risk of serious adverse effects on U.S. financial stability. For example, if a U.S. IHC subsidiary that is a broker-dealer is assumed to fail and enter resolution under the Securities Investor Protection Act (SIPA), the firm should provide an analysis of the potential impacts on funding and asset markets and on prime brokerage clients, bearing in mind the objective of an orderly resolution.

IV. Governance Mechanisms

A firm should identify the governance mechanisms that would ensure that communication and coordination occurs between the boards of the U.S. IHC or a U.S. IHC subsidiary and the foreign parent to facilitate the provision of financial support, or if not forthcoming, any preparatory resolution-related actions to facilitate an orderly resolution.

Playbooks, Foreign Parent Support, and Triggers: Governance playbooks should detail the board and senior management actions of U.S. non-branch material entities that would be needed under the firm's U.S. resolution strategy. The governance playbooks should also include a discussion of (A) the firm's proposed U.S. communications strategy, both internal and external; [17] (B) the fiduciary responsibilities of the applicable board(s) of directors or other similar governing bodies and how planned actions would be consistent with such responsibilities applicable at the time actions are expected to be taken; (C) potential conflicts of interest, including interlocking boards of directors; (D) any employee retention policy; and (E) any other limitations on the authority of the U.S. IHC and the U.S. IHC subsidiary boards and senior management to implement the U.S. resolution strategy. All responsible parties and timeframes for action should be identified. Governance playbooks should be updated periodically for each entity whose governing body would need to act under the firm's U.S. resolution strategy.

In order to meet liquidity needs at the U.S. non-branch material entities, the firm may either fully pre-position liquidity in the U.S. non-branch material entities or develop a mechanism for planned foreign parent support, of any amount not pre-positioned, for the successful execution of the U.S. strategy. Mechanisms to

freely available, the HQLA must be free of legal, regulatory, contractual, and other restrictions on the ability of the material entity to liquidate, sell, or transfer the asset.

[15] ''Model'' refers to the set of calculations required by Regulation YY that estimate the U.S. IHC's liquidity position.

[16] The U.S. IHC should calculate its cash-flow sources from its affiliates consistent with the net internal stressed cash-flow need calculation in § 252.157(c)(2)(iv) of Regulation YY.

[17] External communications include those with U.S. and foreign authorities and other external stakeholders.

support readily available liquidity may include a term liquidity facility between the U.S. IHC and the foreign parent that can be drawn as needed and as informed by the firm's RLEN estimates and liquidity positioning. The plan should include analysis of how the U.S. IHC/foreign parent facility is funded or buffered for by the foreign parent. The sufficiency of the liquidity should be informed by the firm's RLAP and RLEN estimates for the U.S. non-branch material entities. Additionally, the plan should include analysis of the potential challenges to the planned foreign parent support mechanism and associated mitigants. Where applicable, the analysis should discuss applicable non-U.S. law and cross-border legal challenges (*e.g.,* challenges related to enforcing contracts governed by foreign law). The analysis should identify the mitigant(s) to such challenges that the firm considers most effective.

The firm should be prepared to increase communication and coordination at the appropriate time in order to mitigate financial, operational, legal, and regulatory vulnerabilities. To facilitate this communication and coordination, the firm should establish clearly identified triggers linked to specific actions for:

(A) The escalation of information to U.S. senior management, U.S. risk committee and U.S. governing bodies to potentially take the corresponding actions as the U.S. operations experience material financial distress, leading eventually to the decision to implement the U.S. resolution strategy.

i. Triggers should identify when and under what conditions the U.S. material entities would transition from business-as-usual conditions to a stress period.

ii. Triggers should also take into consideration changes in the foreign parent's condition from business-as-usual conditions through resolution.

(B) The escalation of information to and discussions with the appropriate governing bodies to confirm whether the governing bodies are able and willing to provide financial resources to support U.S. operations.

i. Triggers should be based on the firm's methodology for forecasting the liquidity and capital needed to facilitate the U.S. strategy. For example, triggers may be established that reflect U.S. non-branch material entities' financial resources approaching RCEN/RLEN estimates, with corresponding actions to confirm the foreign parent's financial capability and willingness to provide sufficient support.

Corresponding escalation procedures, actions, and timeframes should be constructed so that breach of the triggers will allow prerequisite actions to be completed. For example, breach of the triggers needs to occur early enough to provide for communication, coordination, and confirmation of the provision of resources from the foreign parent.

Support Within the United States: If the plan provides for the provision of capital and liquidity by a U.S. material entity (*e.g.,* the U.S. IHC) to its U.S. affiliates prior to the U.S. IHC's bankruptcy filing (Support), the plan should also include a detailed legal analysis of the potential state law and bankruptcy law challenges and mitigants to providing the Support. Specifically, the analysis should identify potential legal obstacles and explain how the firm would seek to ensure that Support would be provided as planned. Legal obstacles include claims of fraudulent transfer, preference, breach of fiduciary duty, and any other applicable legal theory identified by the firm. The analysis also should include related claims that may prevent or delay an effective recapitalization, such as equitable claims to enjoin the transfer (*e.g.,* imposition of a constructive trust by the court). The analysis should apply the actions contemplated in the plan regarding each element of the claim, the anticipated timing for commencement and resolution of the claims, and the extent to which adjudication of such claim could affect execution of the firm's U.S. resolution strategy. The analysis should include mitigants to the potential challenges to the planned Support. The plan should identify the mitigant(s) to such challenges that the firm considers most effective.

Furthermore, the plan should describe key motions to be filed at the initiation of any bankruptcy proceeding related to (as appropriate) asset sales and other non-routine matters.

V. Operational

Payment, Clearing, and Settlement Activities

Framework. Maintaining continuity of payment, clearing, and settlement (PCS) services is critical for the orderly resolution of firms that are either users or providers,[18] or both, of PCS services. A firm should demonstrate capabilities for continued access to PCS services essential to an orderly resolution under its U.S. resolution strategy through a framework to support such access by:

- Identifying clients,[19] FMUs, and agent banks as key from the firm's perspective for the firm's U.S. material entities, identified critical operations, and core business lines, using both quantitative (volume and value)[20] and qualitative criteria;
- Mapping U.S. material entities, identified critical operations, core business lines, and key clients of the firm's U.S. operations to both key FMUs and key agent banks; and
- Developing a playbook for each key FMU and key agent bank essential to an orderly resolution under its U.S. resolution strategy that reflects the firm's role(s) as a user and/or provider of PCS services.

The framework should address both direct relationships (*e.g.,* a firm's direct membership in an FMU, a firm's provision of clients with PCS services through its own operations in the United States, or a firm's contractual relationship with an agent bank) and indirect relationships (*e.g.,* a firm's provision of clients with access to the relevant FMU or agent bank through the firm's membership in or relationship with that FMU or agent bank, or a firm's U.S. and non-U.S. affiliate and branch provision of U.S. material entities and key clients of the firm's U.S. operations with access to an FMU or agent bank). The framework also should address the potential impact of any disruption to, curtailment of, or termination of such direct and indirect relationships on the firm's U.S. material entities, identified critical operations, and core business lines, as well as any corresponding impact on key clients of the firm's U.S. operations.

Playbooks for Continued Access to PCS Services. The firm is expected to provide a playbook for each key FMU and key agent bank that addresses considerations that would assist the firm and key clients of the firm's U.S. operations in maintaining continued access to PCS services in the period leading up to and including the firm's resolution under its U.S. resolution

[18] A firm is a user of PCS services if it accesses PCS services through an agent bank or it uses the services of an FMU through its membership in that FMU or through an agent bank. A firm is a provider of PCS services if it provides PCS services to clients as an agent bank or it provides clients with access to an FMU or agent bank through the firm's membership in or relationship with that service provider. A firm is also a provider if it provides clients with PCS services through the firm's own operations in the United States (*e.g.,* payment services or custody services).

[19] For purposes of this section V, a client is an individual or entity, including affiliates of the firm, to whom the firm provides PCS services and, if credit or liquidity is offered, any related credit or liquidity offered in connection with those services.

[20] In identifying entities as key, examples of quantitative criteria may include: for a client, transaction volume/value, market value of exposures, assets under custody, usage of PCS services, and if credit or liquidity is offered, any extension of related intraday credit or liquidity; for an FMU, the aggregate volumes and values of all transactions processed through such FMU; and for an agent bank, assets under custody, the value of cash and securities settled, and extensions of intraday credit.

strategy. Each playbook should provide analysis of the financial and operational impact of adverse actions that may be taken by a key FMU or a key agent bank and contingency actions that may be taken by the firm. Each playbook also should discuss any possible alternative arrangements that would allow continued access to PCS services for the firm's U.S. material entities, identified critical operations and core business lines, and key clients of the firm's U.S. operations, while the firm is in resolution under its U.S. resolution strategy. The firm is not expected to incorporate a scenario in which it loses key FMU or key agent bank access into its U.S. resolution strategy or its RLEN and RCEN estimates. The firm should continue to engage with key FMUs, key agent banks, and key clients of the firm's U.S. operations, and playbooks should reflect any feedback received during such ongoing outreach.

Content Related to Users of PCS Services. Individual key FMU and key agent bank playbooks should include:

- Descriptions of the firm's relationship as a user, including through indirect access, with the key FMU or key agent bank and the identification and mapping of PCS services to the firm's U.S. material entities, identified critical operations, and core business lines that use those PCS services;
- Discussion of the potential range of adverse actions that may be taken by that key FMU or key agent bank when the firm is in resolution under its U.S. resolution strategy,[21] the operational and financial impact of such actions on the firm's U.S. material entities, identified critical operations, and core business lines, and contingency arrangements that may be initiated by the firm in response to potential adverse actions by the key FMU or key agent bank; and
- Discussion of PCS-related liquidity sources and uses in business-as-usual (BAU), in stress, and in the resolution period, presented by currency type (with U.S. dollar equivalent) and by U.S. material entity.
  - PCS Liquidity Sources: These may include the amounts of intraday extensions of credit, liquidity buffer, inflows from FMU participants, and prefunded amounts of key clients of the firm's U.S. operations in BAU, in stress, and in the resolution period. The playbook also should describe intraday credit arrangements (*e.g.,* facilities of the key FMU, key agent bank, or a central bank) and any similar custodial arrangements that allow ready access to a firm's funds for PCS-related key FMU and key agent bank obligations (including margin requirements) in various currencies, including placements of firm liquidity at central banks, key FMUs, and key agent banks.
  - PCS Liquidity Uses: These may include margin and prefunding by the firm and key clients of the firm's U.S. operations, and intraday extensions of credit, including incremental amounts required during resolution.
  - Intraday Liquidity Inflows and Outflows: The playbook should describe the firm's ability to control intraday liquidity inflows and outflows and to identify and prioritize time-specific payments. The playbook also should describe any account features that might restrict the firm's ready access to its liquidity sources.

Content Related to Providers of PCS Services.[22] Individual key FMU and key agent bank playbooks should include:

- Identification and mapping of PCS services to the firm's U.S. material entities, identified critical operations, and core business lines that provide those PCS services, and a description of the scale and the way in which each provides PCS services;
- Identification and mapping of PCS services to key clients of the firm's U.S. operations to whom the firm's U.S. material entities, identified critical operations, and core business lines provide such PCS services and any related credit or liquidity offered in connection with such services;
- Discussion of the potential range of firm contingency arrangements available to minimize disruption to the provision of PCS services to key clients of the firm's U.S. operations, including the viability of transferring activity and any related assets of key clients of the firm's U.S. operations, as well as any alternative arrangements that would allow the key clients of the firm's U.S. operations continued access to PCS services if the firm could no longer provide such access (*e.g.,* due to the firm's loss of key FMU or key agent bank access), and the financial and operational impacts of such arrangements from the firm's perspective;
- Descriptions of the range of contingency actions that the firm may take concerning its provision of intraday credit to key clients of the firm's U.S. operations, including analysis quantifying the potential liquidity the firm could generate by taking such actions in stress and in the resolution period, such as (i) requiring key clients of the firm's U.S. operations to designate or appropriately pre-position liquidity, including through prefunding of settlement activity, for PCS-related key FMU and key agent bank obligations at specific material entities of the firm (*e.g.,* direct members of key FMUs) or any similar custodial arrangements that allow ready access to funds for such obligations in various currencies of key clients of the firm's U.S. operations; (ii) delaying or restricting PCS activity of key clients of the firm's U.S. operations; and (iii) restricting, imposing conditions upon (*e.g.,* requiring collateral), or eliminating the provision of intraday credit or liquidity to key clients of the firm's U.S. operations; and
- Descriptions of how the firm will communicate to key clients of the firm's U.S. operations the potential impacts of implementation of any identified contingency arrangements or alternatives, including a description of the firm's methodology for determining whether any additional communication should be provided to some or all key clients of the firm's U.S. operations (*e.g.,* due to BAU usage of that access and/or related intraday credit or liquidity of the key client of the firm's U.S. operations), and the expected timing and form of such communication.

Capabilities. Firms are expected to have and describe capabilities to understand, for each U.S. material entity, its obligations and exposures associated with PCS activities, including contractual obligations and commitments. For example, firms should be able to:

- Track the following items by U.S. material entity and, with respect to customers, counterparties, and agents and service providers, by location/jurisdiction:
  - PCS activities, with each activity mapped to the relevant material entities and core business lines;[23]
  - Customers and counterparties for PCS activities, including values and volumes of various transaction types, as well as used and unused capacity for all lines of credit;[24]

[21] Examples of potential adverse actions may include increased collateral and margin requirements and enhanced reporting and monitoring.

[22] Where a firm is a provider of PCS services through the firm's own operations in the United States, the firm is expected to produce a playbook for the U.S. material entities that provide those services, addressing each of the items described under ''Content Related to Providers of PCS Services,'' which include contingency arrangements to permit the firm's key clients of the firm's U.S. operations to maintain continued access to PCS services.

[23] 12 CFR 243.5(e)(12); 12 CFR 381.5(e)(12).

[24] *Id.*

○ Exposures to and volumes transacted with FMUs, Nostro agents, and custodians; and [25]

○ Services provided and service level agreements for other current agents and service providers (internal and external).[26]

• Assess the potential effects of adverse actions by FMUs, Nostro agents, custodians, and other agents and service providers, including suspension or termination of membership or services, on the firm's U.S. operations and customers and counterparties of those U.S. operations; [27]

• Develop contingency arrangements in the event of such adverse actions; [28] and

• Quantify the liquidity needs and operational capacity required to meet all PCS obligations, including any change in demand for and sources of liquidity needed to meet such obligations.

Managing, Identifying, and Valuing Collateral: The firm is expected to have and describe its capabilities to manage, identify, and value the collateral that the U.S. non-branch material entities receive from and post to external parties and affiliates. Specifically, the firm should:

• Be able to query and provide aggregate statistics for all qualified financial contracts concerning cross-default clauses, downgrade triggers, and other key collateral-related contract terms—not just those terms that may be impacted in an adverse economic environment—across contract types, business lines, legal entities, and jurisdictions;

• Be able to track both firm collateral sources (*i.e.,* counterparties that have pledged collateral) and uses (*i.e.,* counterparties to whom collateral has been pledged) at the CUSIP level on at least a t+1 basis;

• Have robust risk measurements for cross-entity and cross-contract netting, including consideration of where collateral is held and pledged;

• Be able to identify CUSIP and asset class level information on collateral pledged to specific central counterparties by legal entity on at least a t+1 basis;

• Be able to track and report on inter-branch collateral pledged and received on at least a t+1 basis and have clear policies explaining the rationale for such inter-branch pledges, including any regulatory considerations; and

• Have a comprehensive collateral management policy that outlines how the firm as a whole approaches collateral and serves as a single source for governance.[29]

In addition, as of the conclusion of any business day, the firm should be able to:

• Identify the legal entity and geographic jurisdiction where counterparty collateral is held;

• Document all netting and re-hypothecation arrangements with affiliates and external parties, by legal entity; and

• Track and manage collateral requirements associated with counterparty credit risk exposures between affiliates, including foreign branches.

At least on a quarterly basis, the firm should be able to:

• Review the material terms and provisions of International Swaps and Derivatives Association Master Agreements and the Credit Support Annexes, such as termination events, for triggers that may be breached as a result of changes in market conditions;

• Identify legal and operational differences and potential challenges in managing collateral within specific jurisdictions, agreement types, counterparty types, collateral forms, or other distinguishing characteristics; and

• Forecast changes in collateral requirements and cash and non-cash collateral flows under a variety of stress scenarios.

Management Information Systems: The firm should have the management information systems (MIS) capabilities to readily produce data on a U.S. legal entity basis (including any U.S. branch) and have controls to ensure data integrity and reliability, as described below.[30] The firm also should perform a detailed analysis of the specific types of financial and risk data that would be required to execute the U.S. resolution strategy and how frequently the firm would need to produce the information, with the appropriate level of granularity.

A firm is expected to have and describe capabilities to produce the following types of information by material entity on a timely basis:

• Financial statements for each material entity (at least monthly);

• External and inter-affiliate credit exposures, both on- and off-balance sheet, by type of exposure, counterparty, maturity, and gross payable and receivable;

• Gross and net risk positions with internal and external counterparties;

• Guarantees, cross holdings, financial commitments and other transactions between material entities;

• Data to facilitate third-party valuation of assets and businesses, including risk metrics;

• Key third party contracts, including the provider, provider's location, service(s) provided, legal entities that are a party to or a beneficiary of the contract, and key contractual rights (for example, termination and change in control clauses);

• Legal agreement information, including parties to the agreement and key terms and interdependencies (for example, change in control, collateralization, governing law, termination events, guarantees, and cross-default provisions);

• Service level agreements between affiliates, including the service(s) provided, the legal entity providing the service, legal entities receiving the service, and any termination/transferability provisions;

• Licenses and memberships to all exchanges and value transfer networks, including FMUs;

• Key management and support personnel, including dual hatted employees, and any associated retention agreements;

• Agreements and other legal documents related to property, including facilities, technology systems, software, and intellectual property rights. The information should include ownership, physical location, where the property is managed and names of legal entities and lines of business that the property supports; and

• Updated legal records for domestic and foreign entities, including entity type and purpose (for example, holding company, bank, broker dealer, and service entity), jurisdiction(s), ownership, and regulator(s).

Shared and Outsourced Services: The firm should maintain a fully actionable implementation plan to ensure the continuity of shared services that support identified critical operations [31] and robust arrangements to support the continuity of shared and outsourced services, including, without limitation, appropriate plans to retain key personnel relevant to the execution of the firm's strategy. If a material entity provides shared services that support

[25] 12 CFR 252.156(g).

[26] 12 CFR 243.5(f)(l)(i); 12 CFR 381.5(f)(1)(i).

[27] 12 CFR 252.156(e).

[28] *Id.*

[29] The policy may reference subsidiary or related policies already in place, as implementation may differ based on business line or other factors.

[30] MIS infrastructure projects were expected to be completed by 2018.

[31] ''Shared services that support identified critical operations'' or ''critical shared services'' are those that support identified critical operations conducted in whole or in material part in the United States.

identified critical operations,[32] and the continuity of these shared services relies on the assumed cooperation, forbearance, or other non-intervention of regulator(s) in any jurisdiction, the Plan should discuss the extent to which the resolution or insolvency of any other group entities operating in that same jurisdiction may adversely affect the assumed cooperation, forbearance, or other regulatory non-intervention. If a material entity providing shared services that support identified critical operations is located outside of the United States, the Plan should discuss how the firm will ensure the operational continuity of such shared services through resolution.

The firm should (A) maintain an identification of all shared services that support identified critical operations; (B) maintain a mapping of how/where these services support U.S. core business lines and identified critical operations; (C) incorporate such mapping into legal entity rationalization criteria and implementation efforts; and (D) mitigate identified continuity risks through establishment of service-level agreements (SLAs) for all critical shared services.

SLAs should fully describe the services provided, reflect pricing considerations on an arm's-length basis where appropriate, and incorporate appropriate terms and conditions to (A) prevent automatic termination upon certain resolution-related events and (B) achieve continued provision of such services during resolution.[33] The firm should also store SLAs in a central repository or repositories located in or immediately accessible from the U.S. at all times, including in resolution (and subject to enforceable access arrangements) in a searchable format. In addition, the firm should ensure the financial resilience of internal shared service providers by maintaining working capital for six months (or through the period of stabilization as required in the firm's U.S. resolution strategy) in such entities sufficient to cover contract costs, consistent with the U.S. resolution strategy. The firm should demonstrate that such working capital is held in a manner that ensures its availability for its intended purpose.

The firm should identify all service providers and critical outsourced services that support identified critical operations and identify any that could not be promptly substituted. The firm should (A) evaluate the agreements governing these services to determine whether there are any that could be terminated upon commencement of any resolution despite continued performance; and (B) update contracts to incorporate appropriate terms and conditions to prevent automatic termination upon commencement of any resolution proceeding and facilitate continued provision of such services. Relying on entities projected to survive during resolution to avoid contract termination is insufficient to ensure continuity. In the Plan, the firm should document the amendment of any such agreements governing these services. The Plan must also discuss arrangements to ensure the operational continuity of shared services that support identified critical operations in resolution in the event of the disruption of those shared services.

A firm is expected to have robust arrangements in place for the continued provision of shared or outsourced services needed to maintain identified critical operations. For example, firms should:

- Evaluate internal and external dependencies and develop documented strategies and contingency arrangements for the continuity or replacement of the shared and outsourced services that are necessary to maintain identified critical operations.[34] Examples may include personnel, facilities, systems, data warehouses, and intellectual property; and
- Maintain current cost estimates for implementing such strategies and contingency arrangements.

Qualified Financial Contracts: The plan should reflect the current state of how the early termination of qualified financial contracts could impact the resolution of the firm's U.S. operations. Specifically, the plan is expected to reflect the firm's progress in implementing the applicable domestic and foreign requirements regarding contractual stays in qualified financial contracts as of the date the firm submits its plan or as of a specified earlier date.

VI. Branches[35]

Mapping: For each U.S. branch that is a material entity, the Plan should identify and map the financial and operational interconnections to identified critical operations, core business lines, and other material entities. The mapping should also identify any interconnections that, if disrupted, would materially affect identified critical operations, core business lines, or U.S. non-branch material entities, or the U.S. resolution strategy.

Continuity of Operations: If the Plan assumes that federal or state regulators, as applicable, do not take possession of any U.S. branch that is a material entity, the Plan must support that assumption.

For any U.S. branch that is significant to the activities of an identified critical operation, the Plan should describe and demonstrate how the branch would continue to facilitate FMU access for identified critical operations and meet funding needs. Such a U.S. branch would also be required to describe how it would meet supervisory requirements imposed by state regulators or the appropriate Federal banking agency, as appropriate, including maintaining a net due to position and complying with heightened asset maintenance requirements.[36] In addition, the plan should describe how such a U.S. branch's third-party creditors would be protected such that the state regulator or appropriate Federal banking agency would allow the branch to continue operations.

To maintain appropriate liquidity for the purposes of resolution planning, a firm should maintain a liquidity buffer sufficient to meet the net cash outflows for its U.S. branches and agencies on an aggregate basis for the first 14 days of a 30-day stress horizon. In determining the aggregate need of the branches and agencies, the firm should calculate its liquidity position with respect to its foreign parent, U.S. IHC, and other affiliates separately from its liquidity position with respect to external parties, and cannot offset inflows from affiliated parties against outflows to external parties. In addition, a firm may use cash-flow sources from its affiliates to a branch or agency to offset cash-flow needs of its affiliates from a branch or agency only to the extent that the term of the cash-flow source from the affiliates is the same as, or shorter than, the term of the cash-flow need of the affiliate. This assumption addresses the scenario where the head office may be unable or unwilling to return funds to the branch or agency when those funds are most needed.

Impact of the Cessation of Operations: The firm must provide an analysis of the impact of the cessation of operations of

[32] This should be interpreted to include data access and intellectual property rights.

[33] The firm should consider whether these SLAs should be governed by the laws of a U.S. state and expressly subject to the jurisdiction of a court in the U.S.

[34] 12 CFR 243.5(g); 12 CFR 381.5(g).

[35] Note that the PCS framework guidance in Section V. is not limited to U.S. branches, since continuity of access to PCS activities, including through non-U.S. branches, is likely to be essential to the orderly resolution of a firm's U.S. material entities, identified critical operations, and core business lines.

[36] Firms should take into consideration historical practice, by applicable regulators, regarding asset maintenance requirements imposed during stress.

any U.S. branch that is significant to the activities of an identified critical operation on the firm's FMU access and identified critical operations, even if such scenario is not contemplated as part of the U.S. resolution strategy. The analysis should include a description of how identified critical operations could be transferred to a U.S. IHC subsidiary or sold in resolution, the obstacles presented by the cessation of shared services that support identified critical operations provided by any U.S. branch that is a material entity, and mitigants that could address such obstacles in a timely manner.

VII. Group Resolution Plan

Consistent with the Rule, a firm's resolution plan should include a detailed explanation of how resolution planning for the subsidiaries, branches and agencies, and identified critical operations and core business lines of the firm that are domiciled in the United States or conducted in whole or material part in the United States is integrated into the firm's overall resolution or other contingency planning process. In particular, the plan should describe the impact on U.S. operations of executing the global plan.

VIII. Legal Entity Rationalization And Separability

Legal Entity Rationalization Criteria (LER Criteria): A firm should develop and implement legal entity rationalization criteria that support the firm's U.S. resolution strategy and minimize risk to U.S. financial stability in the event of resolution. LER Criteria should consider the best alignment of legal entities and business lines to improve the resolvability of U.S. operations under different market conditions. LER Criteria should govern the corporate structure and arrangements between the U.S. subsidiaries and U.S. branches in a way that facilitates resolvability of the firm's U.S. operations as the firm's U.S. activities, technology, business models, or geographic footprint change over time.

Specifically, application of the criteria should:

(A) Ensure that the allocation of activities across the firm's U.S. branches and U.S. non-branch material entities support the firm's U.S. resolution strategy and minimize risk to U.S. financial stability in the event of resolution;

(B) Facilitate the recapitalization and liquidity support of U.S. IHC subsidiaries, as required by the firm's U.S. resolution strategy. Such criteria should include clean lines of ownership and clean funding pathways between the foreign parent, the U.S. IHC, and U.S. IHC subsidiaries;

(C) Facilitate the sale, transfer, or wind-down of certain discrete operations within a timeframe that would meaningfully increase the likelihood of an orderly resolution in the United States, including provisions for the continuity of associated services and mitigation of financial, operational, and legal challenges to separation and disposition;

(D) Adequately protect U.S. subsidiary insured depository institutions from risks arising from the activities of any nonbank U.S. subsidiaries (other than those that are subsidiaries of an insured depository institution); and

(E) Minimize complexity that could impede an orderly resolution in the United States and minimize redundant and dormant entities.

These criteria should be built into the firm's ongoing process for creating, maintaining, and optimizing the firm's U.S. structure and operations on a continuous basis.

Separability: The firm should identify discrete U.S. operations that could be sold or transferred in resolution, which would provide optionality in resolution under different market conditions. A firm's separability options should be actionable, and impediments to their projected mitigation strategies should be identified in advance. Firms should consider potential consequences for U.S. financial stability of executing each option, taking into consideration impacts on counterparties, creditors, clients, depositors, and markets for specific assets. The level of detail and analysis should vary based on a firm's risk profile and scope of operations. Additionally, information systems should be robust enough to produce the required data and information needed to execute separability options.

Further, the firm should have, and be able to demonstrate, the capability to populate in a timely manner a data room with information pertinent to a potential divestiture of the business (including, but not limited to, carve-out financial statements, valuation analysis, and a legal risk assessment). Within the plan, the firm should demonstrate how the firm's LER Criteria and implementation efforts meet the guidance above. The plan should also provide the separability analysis noted above. Finally, the plan should include a description of the firm's legal entity rationalization governance process.

IX. Derivatives And Trading Activities

A Specified FBO's plan should address the following areas.

Booking Practices

A firm should have booking practices commensurate with the size, scope, and complexity of its U.S. derivatives and trading activities,[37] including systems capabilities to track and monitor any such activities booked directly into a non-U.S. affiliate. The following booking practices-related capabilities should be addressed in a firm's resolution plan:

Derivatives and trading booking framework. A firm should have a comprehensive booking model framework that articulates the principles, rationales, and approach to implementing its booking practices for all of its U.S. derivatives and trading activities, including derivatives and trading activities originated from U.S. entities [38] that are booked directly into a non-U.S. affiliate.[39] The framework and its underlying components should be documented and adequately supported by internal controls (*e.g.,* procedures, systems, processes). Taken together, the booking framework and its components should provide transparency with respect to (i) what is being booked (*e.g.,* product, counterparty), (ii) where it is being originated and booked (*e.g.,* legal entity, geography), (iii) by whom it is originated and booked (*e.g.,* business or trading desk), (iv) why it is booked that way (*e.g.,* drivers or rationales for that arrangement), and (v) what controls the firm has in place to monitor and manage those practices (*e.g.,* governance or information systems).[40]

The firm's resolution plan should include detailed descriptions of the framework and each of its material components. In particular, a firm's resolution plan should include

[37] ''U.S. derivatives and trading activities'', means all derivatives and trading activities that are: (1) Related to a firm's identified critical operations or core business lines, including any such activities booked directly into a non-U.S. affiliate; (2) conducted on behalf of the firm, its clients, or counterparties that are originated from, booked into, traded through, or otherwise conducted (in whole or in material part) in a U.S. entity (as defined below); or (3) both of the foregoing. A firm should identify its U.S. derivatives and trading activities pursuant to a methodology and justify the methodology used.

[38] ''U.S. entities'' means U.S. IHC subsidiaries and material entity branches.

[39] Activities ''originated'' from U.S. entities are those activities transacted or arranged by, or on behalf of those U.S. entities and their clients and counterparties, including any such activity for which the U.S. entity is compensated (directly or indirectly) by a non-U.S. affiliate. These activities also include, for example, those that are sourced or executed through personnel employed by or acting on behalf of a U.S. entity. The agencies would expect that a U.S. entity that is significant to the origination of activities for an identified critical operation or core business line would be designated as a U.S. material entity.

[40] The description of controls should include any components of any firm-wide market, credit, or liquidity risk management framework that is material to the management of the firm's U.S. derivatives and trading activities.

descriptions of documented booking models covering the full range of its U.S. derivatives and trading activities.[41] These descriptions should provide clarity with respect to the underlying booking flows (*e.g.,* the mapping of trade flows based on multiple trade characteristics as decision points that determine on which entity a trade is directly booked and the applicability of any risk transfer arrangements). Furthermore, a firm's resolution plan should describe its end-to-end booking and reporting processes, including a description of the current scope of automation (*e.g.,* automated trade flows, detective monitoring) of the systems controls applied to the firm's documented booking models. The plan should also discuss why the firm believes its current (or planned) scope of automation is sufficient for managing its U.S. derivatives and trading activities during the execution of its U.S. resolution strategy.[42]

Derivatives and trading entity analysis and reporting. A firm should have the ability to identify, assess, and report on each U.S. entity that originates or otherwise conducts (in whole or in material part) any significant aspect of the firm's U.S. derivatives and trading activities (a ''derivatives or trading entity''). First, the firm's resolution plan should describe its method (which may include both qualitative and quantitative criteria) for evaluating the significance of each derivatives or trading entity both with respect to the firm's current U.S. derivatives and trading activities and its U.S. resolution strategy.[43] Second, a firm's resolution plan should demonstrate (including through use of illustrative samples) the firm's ability to readily generate current derivatives or trading entity profiles that (i) cover all derivatives or trading entities, (ii) are reportable in a consistent manner, and (iii) include information regarding current legal ownership structure, business activities and volume, and risk profile of the entity (including relevant risk transfer arrangements).

U.S. Activities Monitoring

A firm should be able to assess how the management of U.S. derivatives and trading activities could be affected in the period leading up to and during the execution of its U.S. resolution strategy, including disruptions that could affect materially the funding or operations of the U.S. entities that conduct the U.S. derivatives and trading activities or their clients and counterparties. Therefore, a firm should have capabilities to provide timely transparency into the management of its U.S. derivatives and trading activities, including such activities booked directly into a non-U.S. affiliate, in the period leading up to and during the execution of its U.S. resolution strategy by maintaining a monitoring framework for U.S. derivatives and trading activities, which consists of at least the following two components:

1. A method for identifying U.S. derivatives and trading activities, and measuring, monitoring, and reporting on those activities on a business line and legal entity basis; and
2. A method for identifying, assessing, and reporting the potential impact on (i) clients and counterparties of U.S. entities that conduct the U.S. derivatives and trading activities and (ii) any related risk transfer arrangements[44] among and between U.S. entities and their non-U.S. affiliates.

Prime Brokerage Customer Account Transfers

A firm should have the operational capacity to facilitate the orderly transfer of U.S. prime brokerage accounts,[45] including account positions of a client of the firm's U.S. prime brokerage business that are booked directly into a non-U.S. affiliate, to peer prime brokers in periods of material financial distress and during the execution of its U.S. resolution strategy. The firm's plan should include an assessment of how it would transfer such accounts. This assessment should be informed by clients' relationships with other prime brokers, the use of automated and manual transaction processes, clients' overall long and short positions as facilitated by the firm, and the liquidity of clients' portfolios. The assessment should also analyze the risks and loss mitigants of customer-to-customer internalization (*e.g.,* the inability to fund customer longs with customer shorts) and operational challenges (including insufficient staffing) that the firm may experience in effecting the scale and speed of prime brokerage account transfers envisioned under the firm's U.S. resolution strategy.

In addition, a firm should describe and demonstrate its ability to segment and analyze the quality and composition of U.S. prime brokerage account balances based on a set of well-defined and consistently applied segmentation criteria (*e.g.,* size, single-prime, platform, use of leverage, non-rehypothecatable securities, liquidity of underlying assets). The capabilities should cover U.S. prime brokerage account balances and the resulting segments should represent a range in potential transfer speed (*e.g.,* from fastest to longest to transfer, from most liquid to least liquid). The selected segmentation criteria should reflect characteristics[46] that the firm believes could affect the speed at which the U.S. prime brokerage account would be transferred to an alternate prime broker.

Portfolio Segmentation

A firm should have the capabilities to produce analysis that reflects derivatives portfolio[47] segmentation and differentiation of assumptions, taking into account trade-level characteristics. More specifically, a firm should have systems capabilities that would allow it to produce a spectrum of derivatives portfolio segmentation analysis using multiple segmentation dimensions for each U.S. entity with a derivatives portfolio—namely, (1) trading desk or product, (2) cleared vs. clearable vs. non-clearable trades, (3) counterparty type, (4) currency, (5) maturity, (6) level of collateralization, and (7) netting set.[48] A firm should also

[41] The booking models should represent the vast majority (*e.g.,* 95 percent) of a firm's U.S. derivatives and trading activities, including U.S. derivatives and trading transactions that are originated from U.S. entities and booked directly into a non-U.S. affiliate, measured by, for example, trade notional and gross market value (for derivatives) and client positions and balances (for prime brokerage client accounts).

[42] Effective preventative (up-front) and detective (post-booking) controls embedded in a firm's booking processes can help avoid and/or timely remediate trades that do not align with a documented booking model or related risk limit. Firms typically use a combination of manual and automated control functions. Although automation may not be best suited for all control functions, as compared to manual methods, it can improve consistency and traceability with respect to booking practices. However, non-automated methods also can be effective when supported by other internal controls (*e.g.,* robust detective monitoring, escalation protocols).

[43] The firm should leverage any existing methods and criteria it uses for other entity assessments (*e.g.,* legal entity rationalization or the prepositioning of internal loss-absorbing resources). The firm's method for determining the significance of derivatives or trading entities may diverge from the parameters for material entity designation under the Rule (*i.e.,* entities significant to the activities of an identified critical operation or core business line); however, any differences should be adequately supported and explained.

[44] For example, risk transfer arrangements might include transfer pricing, profit sharing, loss limiting, or intragroup hedging arrangements.

[45] ''U.S. prime brokerage account'' or ''U.S. prime brokerage account balances'' should include the account positions and balances of a client of the firm's U.S. prime brokerage business, regardless of where those positions or balances are booked.

[46] For example, relevant characteristics might include product, size, clearability, currency, maturity, level of collateralization, and other risk characteristics.

[47] A firm's derivatives portfolios include its derivatives positions and linked non-derivatives trading positions.

[48] The enumerated segmentation dimensions are not intended as an exhaustive list of relevant

have the capabilities to segment and analyze the full contractual maturity (run-off) profile of the derivatives portfolios in its U.S. entities. The firm's resolution plan should describe and demonstrate the firm's ability to segment and analyze the derivatives portfolios booked into its U.S. entities using the relevant segmentation dimensions and to report the results of such segmentation and analysis.

Derivatives Stabilization and De-Risking Strategy

To the extent the U.S. resolution strategy assumes the continuation of a U.S. IHC subsidiary with a derivatives portfolio after the entry of the U.S. IHC into a U.S. bankruptcy proceeding (surviving derivatives subsidiary), the firm's plan should provide a detailed analysis of the strategy to stabilize and de-risk any derivatives portfolio of the surviving derivatives subsidiary (U.S. derivatives strategy) that has been incorporated into its U.S. resolution strategy.[49] In developing its U.S. derivatives strategy, a firm should apply the following assumption constraints:

• *OTC derivatives market access:* At or before the start of the resolution period, each surviving derivatives subsidiary should be assumed to lack an investment grade credit rating (*e.g.,* unrated or downgraded below investment grade). Each surviving derivatives subsidiary also should be assumed to have failed to establish or reestablish investment grade status for the duration of the resolution period, unless the plan provides well-supported analysis to the contrary. As the subsidiary is not investment grade, it further should be assumed that each surviving derivatives subsidiary has no access to bilateral OTC derivatives markets and must use exchange-traded or centrally cleared instruments for any new hedging needs that arise during the resolution period. Nevertheless, a firm may assume the ability to engage in certain risk-reducing derivatives trades with bilateral OTC derivatives counterparties during the resolution period to facilitate novations with third parties and to close out inter-affiliate trades.[50]

• *Early exits (break clauses):* A firm should assume that counterparties (both external and affiliates) will exercise any contractual termination or other right, including any rights stayed by contract (including amendments) or in compliance with the rules establishing restrictions on qualified financial contracts of the Board, the FDIC, or the Office of the Comptroller of the Currency[51] or any other regulatory requirements, (i) that is available to the counterparty at or following the start of the resolution period; and (ii) if exercising such right would economically benefit the counterparty (counterparty-initiated termination).

• *Time horizon:* The duration of the resolution period should be between 12 and 24 months. The resolution period begins immediately after the U.S. IHC bankruptcy filing and extends through the completion of the U.S. resolution strategy.[52]

A firm's analysis of its U.S. derivatives strategy should take into account (i) the starting profile of any derivatives portfolio of each surviving derivatives subsidiary (*e.g.,* nature, concentration, maturity, clearability, liquidity of positions); (ii) the profile and function of any surviving derivatives subsidiary during the resolution period; (iii) the means, challenges, and capacity of the surviving derivatives subsidiary to manage and de-risk its derivatives portfolios (*e.g.,* method for timely segmenting, packaging, and selling the derivatives positions; challenges with novating less liquid positions; re-hedging strategy); (iv) the financial and operational resources required to effect the derivatives strategy; and (v) any potential residual portfolio (further discussed below). In addition, the firm's resolution plan should address the following areas in the analysis of its derivatives strategy:

Forecasts of resource needs. The forecasts of capital and liquidity resource needs of U.S. IHC subsidiaries required to support adequately the firm's U.S. derivatives strategy should be incorporated into the firm's RCEN and RLEN estimates for its overall U.S. resolution strategy. These include, for example, the costs and liquidity flows resulting from (i) the close-out of OTC derivatives, (ii) the hedging of derivatives portfolios, (iii) the quantified losses that could be incurred due to basis and other risks that would result from hedging with only exchange-traded and centrally cleared instruments in a severely adverse stress environment, and (iv) operational costs.[53]

Sensitivity analysis. A firm should have a method to apply sensitivity analyses to the key drivers of the derivatives-related costs and liquidity flows under its U.S. resolution strategy. A firm's resolution plan should describe its method for (i) evaluating the materiality of assumptions and (ii) identifying those assumptions (or combinations of assumptions) that constitute the key drivers for its forecasts of derivatives-related operational and financial resource needs under the U.S. resolution strategy. In addition, using its U.S. resolution strategy as a baseline, the firm's resolution plan should describe and demonstrate its approach to testing the sensitivities of the identified key drivers and the potential impact on its forecasts of resource needs.[54]

Potential residual derivatives portfolio. A firm's resolution plan should include a method for estimating the composition of any potential residual derivatives portfolio transactions booked in a U.S. IHC subsidiary remaining at the end of the resolution period under its U.S.

dimensions. With respect to any product or asset class, a firm may have reasons for not capturing data on (or not using) one or more of the enumerated segmentation dimensions. In that case, however, the firm should explain those reasons.

[49] Subject to the relevant constraints, a firm's U.S. derivatives strategy may take the form of a going-concern strategy, an accelerated de-risking strategy (*e.g.,* active wind-down) or an alternative, third strategy so long as the firm's resolution plan adequately supports the execution of the chosen strategy. For example, a firm may choose a going-concern scenario (*e.g.,* surviving derivatives subsidiary reestablishes investment grade status and does not enter any wind-down) as its derivatives strategy. Likewise, a firm may choose to adopt a combination of going-concern and accelerated de-risking scenarios as its U.S. derivatives strategy. For example, the U.S. derivatives strategy could be a stabilization scenario for the U.S. bank entity and an accelerated de-risking scenario for U.S. broker-dealer entities.

[50] A firm may engage in bilateral OTC derivatives trades with, for example, (i) external counterparties, to effect the novation of the firm's side of a derivatives contract to a new, acquiring counterparty; and (ii) inter-affiliate counterparties, where the trades with inter-affiliate counterparties do not materially increase either the credit exposure of any participating counterparty or the market risk of any such counterparty on a standalone basis, after taking into account any hedging with exchange-traded and centrally-cleared instruments. The firm should provide analysis to support the risk of the trade on the basis of information that would be known to the firm at the time of the transaction.

[51] *See* 12 CFR part 47 (OCC); 252, subpart I (Board); 382 (FDIC).

[52] The firm may consider a resolution period of less than 12 months as long as the length of the resolution period is adequately supported by the firm's analysis of the size, composition, complexity, and maturity profile of the derivatives portfolios in its U.S. IHC subsidiaries.

[53] A firm may choose not to isolate and separately model the operational costs solely related to executing its derivatives strategy. However, the firm should provide transparency around operational cost estimation at a more granular level than material entity (*e.g.,* business line level within a material entity, subject to wind-down).

[54] For example, key drivers of derivatives-related costs and liquidity flows might include the timing of derivatives unwind, cost of capital-related assumptions (*e.g.,* target return on equity, discount rate, weighted average life, capital constraints, tax rate), operational cost reduction rate, and operational capacity for novations. Other examples of key drivers likely also include central counterparty margin flow assumptions and risk-weighted asset forecast assumptions.

resolution strategy. The firm's plan also should provide detailed descriptions of the trade characteristics used to identify such potential residual portfolio and of the resulting trades (or categories of trades).[55] A firm should assess the risk profile of such potential residual portfolio (including its anticipated size, composition, complexity, and counterparties), and the potential counterparty and market impacts of non-performance by the firm on the stability of U.S. financial markets (*e.g.,* on funding markets, on underlying asset markets, on clients and counterparties).

Non-surviving entity analysis. To the extent the U.S. resolution strategy assumes a U.S. IHC subsidiary with a derivatives portfolio enters its own resolution proceeding after the entry of the U.S. IHC into a U.S. bankruptcy proceeding (a non-surviving derivatives subsidiary), the firm should provide a detailed analysis of how the non-surviving derivatives subsidiary's resolution can be accomplished within a reasonable period of time and in a manner that substantially mitigates the risk of serious adverse effects on U.S. financial stability and on the orderly execution of the firm's U.S. resolution strategy. In particular, the firm should provide an analysis of the potential impacts on funding markets, on underlying asset markets, on clients and counterparties (including affiliates), and on the firm's U.S. resolution strategy.

X. Format and Structure of Plans

Format of Plan

Executive Summary. The Plan should contain an executive summary consistent with the Rule, which must include, among other things, a concise description of the key elements of the firm's U.S. strategy for an orderly resolution. In addition, the executive summary should include a discussion of the firm's assessment of any impediments to the firm's U.S. resolution strategy and its execution, as well as the steps it has taken to address any identified impediments.

Narrative. The Plan should include a strategic analysis consistent with the Rule. This analysis should take the form of a concise narrative that enhances the readability and understanding of the firm's discussion of its U.S. strategy for rapid and orderly resolution in bankruptcy or other applicable insolvency regimes (Narrative). The Narrative also should include a high-level discussion of how the firm is addressing key vulnerabilities jointly identified by the Agencies. This is not an exhaustive list and does not preclude identification of further vulnerabilities or impediments.

Appendices. The Plan should contain a sufficient level of detail and analysis to substantiate and support the strategy described in the Narrative. Such detail and analysis should be included in appendices that are distinct from and clearly referenced in the related parts of the Narrative (Appendices).

Public Section. The Plan must be divided into a public section and a confidential section consistent with the requirements of the Rule.

Other Informational Requirements. The Plan must comply with all other informational requirements of the Rule. The firm may incorporate by reference previously submitted information as provided in the Rule.

Guidance Regarding Assumptions

1. The Plan should be based on the current state of the applicable legal and policy frameworks. Pending legislation or regulatory actions may be discussed as additional considerations.

2. The firm must submit a plan that does not rely on the provision of extraordinary support by the United States or any other government to the firm or its subsidiaries to prevent the failure of the firm.

3. The firm should not assume that it will be able to sell identified critical operations or core business lines, or that unsecured funding will be available immediately prior to filing for bankruptcy.

4. The Plan should assume the Dodd-Frank Act Stress Test (DFAST) severely adverse scenario for the first quarter of the calendar year in which the Plan is submitted is the domestic and international economic environment at the time of the firm's failure and throughout the resolution process.

5. The resolution strategy may be based on an idiosyncratic event or action. The firm should justify use of that assumption, consistent with the conditions of the economic scenario.

6. Within the context of the applicable idiosyncratic scenario, markets are functioning and competitors are in a position to take on business. If a firm's Plan assumes the sale of assets, the firm should take into account all issues surrounding its ability to sell in market conditions present in the applicable economic condition at the time of sale (*i.e.,* the firm should take into consideration the size and scale of its operations as well as issues of separation and transfer.)

7. The firm should not assume any waivers of section 23A or 23B of the Federal Reserve Act in connection with the actions proposed to be taken prior to or in resolution.

8. The firm may assume that its depository institutions will have access to the Discount Window only for a few days after the point of failure to facilitate orderly resolution. However, the firm should not assume its subsidiary depository institutions will have access to the Discount Window while critically undercapitalized, in FDIC receivership, or operating as a bridge bank, nor should it assume any lending from a Federal Reserve credit facility to a non-bank affiliate.

Financial Statements and Projections

The Plan should include the actual balance sheet for each material entity and the consolidating balance sheet adjustments between material entities as well as pro forma balance sheets for each material entity at the point of failure and at key junctures in the execution of the resolution strategy. It should also include projected statements of sources and uses of funds for the interim periods. The pro forma financial statements and accompanying notes in the Plan must clearly evidence the failure trigger event; the Plan's assumptions; and any transactions that are critical to the execution of the Plan's preferred strategy, such as recapitalizations, the creation of new legal entities, transfers of assets, and asset sales and unwinds.

Material Entities

Material entities should encompass those entities, including subsidiaries, branches and agencies (collectively, Offices), which are significant to the activities of an identified critical operation or core business line. If the abrupt disruption or cessation of a core business line might have systemic consequences to U.S. financial stability, the entities essential to the continuation of such core business line should be considered for material entity designation. Material entities should include the following types of entities:

a. Any Office, wherever located, that is significant to the activities of an identified critical operation.

b. Any Office, wherever located, whose provision or support of global treasury operations, funding, or liquidity activities (inclusive of intercompany transactions) is significant to the activities of an identified critical operation.

[55] If, under the firm's U.S. resolution strategy, any derivatives portfolios are transferred during the resolution period by way of a line of business sale (or similar transaction), then those portfolios nonetheless should be included within the firm's potential residual portfolio analysis.

c. Any Office, wherever located, that would provide material operational support in resolution (key personnel, information technology, data centers, real estate or other shared services) to the activities of an identified critical operation.

d. Any Office, wherever located, that is engaged in derivatives booking activity that is significant to the activities of an identified critical operation, including those that conduct either the internal hedge side or the client-facing side of a transaction.

e. Any Office, wherever located, engaged in asset custody or asset management that are significant to the activities of an identified critical operation.

f. Any Office, wherever located, holding licenses or memberships in clearinghouses, exchanges, or other FMUs that are significant to the activities of an identified critical operation.

For each material entity (including a branch), the Plan should enumerate, on a jurisdiction-by-jurisdiction basis, the specific mandatory and discretionary actions or forbearances that regulatory and resolution authorities would take during resolution, including any regulatory filings and notifications that would be required as part of the U.S. resolution strategy, and explain how the Plan addresses the actions and forbearances. The Plan should describe the consequences for the firm's U.S. resolution strategy if specific actions in each jurisdiction were not taken, delayed, or forgone, as relevant.

XI. Public Section

The purpose of the public section is to inform the public's understanding of the firm's resolution strategy and how it works.

The public section should discuss the steps that the firm is taking to improve resolvability under the U.S. Bankruptcy Code. The public section should provide background information on each material entity and should be enhanced by including the firm's rationale for designating material entities. The public section should also discuss, at a high level, the firm's intra-group financial and operational interconnectedness (including the types of guarantees or support obligations in place that could impact the execution of the firm's strategy). There should also be a high-level discussion of the liquidity resources and loss-absorbing capacity of the U.S. IHC.

The discussion of strategy in the public section should broadly explain how the firm has addressed any deficiencies, shortcomings, and other key vulnerabilities that the Agencies have identified in prior Plan submissions. For each material entity, it should be clear how the strategy provides for continuity, transfer, or orderly wind-down of the entity and its operations. There should also be a description of the resulting organization upon completion of the resolution process.

The public section may note that the resolution plan is not binding on a bankruptcy court or other resolution authority and that the proposed failure scenario and associated assumptions are hypothetical and do not necessarily reflect an event or events to which the firm is or may become subject.

Appendix: Frequently Asked Questions

In March 2017, the Agencies issued guidance for use in developing the 2018 resolution plan submissions by certain foreign banking organizations.

In response to frequently asked questions regarding that guidance from the recipients of that guidance, Board and FDIC staff jointly developed answers and provided those answers to the guidance recipients in 2017 so that they could take this information into account in developing their next resolution plan submissions.[56]

The questions in this Appendix:

- Comprise common questions asked by different covered companies. Not every question is applicable to every firm; not every aspect of the proposed guidance applies to each firm's preferred strategy/structure; and
- Reflect updated references to correspond to this proposed guidance for the Specified FBOs (Proposed Guidance).

As indicated below, those questions and answers that are deemed to be no longer meaningful or relevant have not been consolidated in this Appendix and are superseded.

Capital

CAP 1. Capital Pre-Positioning and Balance

Q. How should a firm determine the appropriate balance between resources pre-positioned at the U.S. IHC subsidiaries and held at the U.S. IHC?

A. The Proposed Guidance addresses this issue in the Capital section. The Agencies are not prescribing a specific percentage allocation of resources pre-positioned at the U.S. IHC subsidiaries versus resources held at the U.S. IHC. In considering the balance between certainty and flexibility, the Agencies note that the risk profile of each U.S. IHC subsidiary should inform the ''unanticipated losses'' at the entity, which should be taken into account in determining the appropriate balance.

[56] The FAQs represent the views of staff of the Board of Governors of the Federal Reserve System and the Federal Deposit Insurance Corporation and do not bind the Board or the FDIC.

CAP 2. Definition of ''Well-Capitalized'' Status

Q. How should firms apply the term ''well-capitalized''?

A. U.S. non-branch material entities must comply with the capital requirements and expectations of their primary regulator. U.S. non-branch material entities should be recapitalized to meet jurisdictional requirements and to maintain market confidence as required under the U.S. resolution strategy.

CAP 3. RCEN Relationship to DFAST Severely Adverse Scenario

Q. How should the firm's RCEN and RLEN estimates relate to the DFAST Severely Adverse scenario? Can those estimates be recalibrated in actual stress conditions?

A. For resolution plan submission purposes, the estimation of RLEN and RCEN should assume macroeconomic conditions consistent with the DFAST Severely Adverse scenario. However, the RLEN and RCEN methodologies should have the flexibility to incorporate macroeconomic conditions that may deviate from the DFAST Severely Adverse scenario in order to facilitate execution of the U.S. resolution strategy.

CAP 4. Not Consolidated

Liquidity

LIQ 1. Inter-Company ''Frictions''

Q. Can the Agencies clarify what kinds of frictions might occur between affiliates beyond regulatory ring-fencing?

A. Frictions are *any* impediments to the free flow of funds, collateral and other transactions between material entities. Examples include regulatory, legal, financial (*i.e.,* tax consequences), market, or operational constraints or requirements.

LIQ 2. Distinction Between Liquidity Forecasting Periods

Q1. How long is the stabilization period?

A1. The stabilization period begins immediately after the U.S. IHC bankruptcy filing and extends until each material entity reestablishes market confidence. The stabilization period may not be less than 30 days. The reestablishment of market confidence may be reflected by the maintaining, reestablishing, or establishing of investment grade ratings or the equivalent financial condition for each entity. The stabilization period may vary by material entity, given differences in regulatory, counterparty, and other stakeholder interests in each entity.

Q2. How should we distinguish between the runway, resolution, and stabilization periods on the one hand, and RLAP and RLEN on the other, in terms of their length, sequencing, and liquidity thresholds?

A2. The Agencies have not specified a direct mathematical relationship between the runway period, the RLAP model, and RLEN model. As noted in prior guidance, firms may assume a runway period of up to 30 days prior to entering bankruptcy provided the period is sufficient for management to contemplate the necessary actions preceding the filing of bankruptcy. The RLAP model should provide for the adequate sizing and positioning of HQLA at material entities for

anticipated net liquidity outflows for a period of at least 30 days. The RLEN model estimates the liquidity needed after the U.S. IHC's bankruptcy filing to stabilize the surviving material entities and to allow those entities to operate post-filing. See ''LIQ 4. RLEN and Minimum Operating Liquidity (MOL),'' Question 1, for further detail on the components of the RLEN model.

Q3. What is the resolution period?

A3. The resolution period begins immediately after the U.S. IHC's bankruptcy filing and extends through the completion of the U.S. strategy. After the stabilization period (see ''LIQ 2. Distinction between Liquidity Forecasting Periods,'' Question 1, regarding ''stabilization period''), financial statements and projections may be provided at quarterly intervals through the remainder of the resolution period.

LIQ 3. Inter-Affiliate Transaction Assumptions

Q. Does inter-affiliate funding refer to all kinds of intercompany transactions, including both unsecured and secured?

A. Yes.

LIQ 4. RLEN and Minimum Operating Liquidity (MOL)

Q1. How should firms distinguish between the minimum operating liquidity (MOL) and peak funding needs during the RLEN period?

A1. The peak funding needs represent the peak cumulative net out-flows during the stabilization period. The components of peak funding needs, including the monetization of assets and other management actions, should be transparent in the RLEN projections. The peak funding needs should be supported by projections of daily sources and uses of cash for each U.S. IHC subsidiary, incorporating inter-affiliate and third-party exposures. In mathematical terms, RLEN = MOL + peak funding needs during the stabilization period. RLEN should also incorporate liquidity execution needs of the U.S. resolution strategy for derivatives (*see* Derivatives and Trading Activities section).

Q2. Should the MOL per entity make explicit the allocation for intraday liquidity requirements, inter-affiliate and other funding frictions, operating expenses, and working capital needs?

A2. Yes, the components of the MOL estimates for each surviving U.S. IHC subsidiary should be transparent and supported.

Q3. Can MOLs decrease as surviving U.S. IHC subsidiaries wind down?

A3. MOL estimates can decline as long as they are sufficiently supported by the firm's methodology and assumptions.

LIQ 5. Not Consolidated

LIQ 6. Inter-Affiliate Transactions With Optionality

Q. How should firms treat an inter-affiliate transaction with an embedded option that may affect the contractual maturity date?

A. For the purpose of calculating a firm's net liquidity position at a material entity, RLAP and RLEN models should assume that these transactions mature at the earliest possible exercise date; this adjusted maturity should be applied symmetrically to both material entities involved in the transaction.

LIQ 7. Stabilization and Regulatory Liquidity Requirements

Q. As it relates to the RLEN model and actions necessary to re-establish market confidence, what assumptions should firms make regarding compliance with regulatory liquidity requirements?

A. Firms should consider the applicable regulatory expectations for each U.S. IHC subsidiary to achieve the stabilization needed to execute the U.S. resolution strategy. Firms' assumptions in the RLEN model regarding the actions necessary to reestablish market confidence during the stabilization period may vary by U.S. IHC subsidiary, for example, based on differences in regulatory, counterparty, other stakeholder interests, and based on the U.S. resolution strategy for each U.S. IHC subsidiary. See also ''LIQ 2. Distinction between Liquidity Forecasting Periods.''

LIQ 8. HQLA and Assets Not Eligible as HQLA in RLAP and RLEN Models

Q. The Proposed Guidance states that HQLA should be used to meet estimated net liquidity deficits in the RLAP model and that the RLEN estimate should be based on the minimum amount of HQLA required to facilitate the execution of the firm's U.S. resolution strategy. How should firms incorporate any expected liquidity value of assets that are not eligible as HQLA (non-HQLA) into RLAP and RLEN models?

A. A firm's RLAP model should assume that only HQLA are available to meet net liquidity deficits at U.S. IHC subsidiaries. For a firm's RLEN model, firms may incorporate conservative estimates of potential liquidity that may be generated through the monetization of non-HQLA. The estimated liquidity value of non-HQLA should be supported by thorough analysis of the potential market constraints and asset value haircuts that may be required. Assumptions for the monetization of non-HQLA should be consistent with the U.S. resolution strategy for each U.S. IHC subsidiary.

LIQ 9. Components of Minimum Operating Liquidity

Q. Do the agencies have particular definitions of the ''intraday liquidity requirements,'' ''operating expenses,'' and ''working capital needs'' components of minimum operating liquidity (MOL) estimates?

A. No. A firm may use its internal definitions of the components of MOL estimates. The components of MOL estimates should be well-supported by a firm's internal methodologies and calibrated to the specifics of each U.S. IHC subsidiary.

LIQ 10. RLEN Model and Net Revenue Recognition

Q. Can firms assume in the RLEN model that cash-based net revenue generated by U.S. IHC subsidiaries after the U.S. IHC's bankruptcy filing is available to offset estimated liquidity needs?

A. Yes. Firms may incorporate cash revenue generated by U.S. IHC subsidiaries in the RLEN model. Cash revenue projections should be conservatively estimated and consistent with the operating environment and the U.S. strategy for each U.S. IHC subsidiary.

LIQ 11. RLEN Model and Inter-Affiliate Frictions

Q. Can a firm modify its assumptions regarding one or more inter-affiliate frictions during the stabilization or post-stabilization period in the RLEN model?

A. Once a U.S. IHC subsidiary has achieved market confidence necessary for stabilization consistent with the U.S. resolution strategy, a firm may modify one or more inter-affiliate frictions, provided the firm provides sufficient analysis to support this assumption.

LIQ 12. RLEN Relationship to DFAST Severely Adverse Scenario

(See ''CAP 3. RCEN Relationship to DFAST Severely Adverse Scenario'' in the Capital section.)

LIQ 13. Liquidity Positioning and Foreign Parent Support

Q1. May firms consider available liquidity at the foreign parent for meeting RLAP and RLEN estimates for U.S. non-branch material entities?

A1. For a 30-day RLAP model, firms should use the requirements of Regulation YY in estimating the standalone liquidity position of each U.S. non-branch material entities. Firms should not rely on available liquidity at the foreign parent to meet net liquidity outflows of U.S. non-branch material entities. The firm's RLAP model should ensure that the consolidated U.S. IHC holds sufficient HQLA to cover net liquidity outflows of the U.S. non-branch material entities. For an RLAP model that extends beyond 30 days, firms may consider (after 30 days) available liquidity at the foreign parent to meet the needs for U.S. non-branch material entities.

To meet the liquidity needs informed by the RLEN methodology, firms may either fully pre-position liquidity in the U.S. non-branch material entities or develop a mechanism for planned foreign parent support of any amount not pre- positioned for the successful execution of the U.S. strategy. Mechanisms to support readily available liquidity may include a term liquidity facility between the U.S. IHC and the foreign parent that can be drawn as needed. If a firm's plan relies on foreign parent support, the plan should include analysis of how the U.S. IHC/foreign parent facility is funded or buffered for by the foreign parent.

LIQ 14. RLAP Model Time Horizon and Inter-Affiliate Transactions

Q. How should firms treat cash flow sources from affiliates in the RLAP model for models that use time periods in excess of 30 days, given the affiliate cash flow calculation requirements in section 252.157(c)(2)(iv) of Regulation YY?

A. An RLAP model that includes time periods beyond 30 days is not required to adopt the affiliate cash flow calculation requirements in section 252.157(c)(2)(iv) of Regulation YY for inter-affiliate cash flows beyond 30 days. However, beyond 30 days, the RLAP methodology still should take into account for each of the U.S. IHC, U.S. IHC subsidiaries, and any branch that is a material entity the considerations detailed in

(A), (B), and (C) in the RLAP subsection of the Proposed Guidance. *See* Resolution Liquidity Adequacy and Positioning (RLAP) section.

LIQ 15. U.S. Branches and Agencies Liquidity Modeling

Q1. Are firms required to develop a RLAP model for U.S. branches and agencies?

A1. Firms are not required to develop a RLAP model for material U.S. branches and agencies; however, as described in the Liquidity section of the Proposed Guidance, a firm should maintain a liquidity buffer sufficient to meet the net cash outflows for its U.S. branches and agencies on an aggregate basis for the first 14 days of a 30-day stress horizon. These expectations are consistent with the stress testing and liquidity buffer requirements in section 252.157(c)(3) of Regulation YY.

Q2. The Proposed Guidance states that in calculating RLAP estimates the U.S. IHC should calculate its liquidity position with respect to its foreign parent, branches and agencies, and other affiliates separately from its liquidity position with respect to third parties. How should firms interpret the RLAP requirements since RLAP is not required for U.S. branches and agencies?

A2. The RLAP estimates for U.S. non-branch material entities should take into account how cash flows and the stand-alone liquidity profile may be affected by all inter-affiliate transactions, which may include the impact on the U.S. non-branch material entities from flows transacted with U.S. branches and agencies.

LIQ 16. Material Service Entity Liquidity

Q. Is a standalone liquidity position estimate needed for material service entities?

A. For material service entities with no other operations other than providing services only to their affiliates and having no third-party debt obligations, a standalone liquidity position estimate is not required.

Operational: Shared Services

OPS SS 1. Not Consolidated

OPS SS 2. Working Capital

Q1. Must working capital be maintained for third party and internal shared service costs?

A1. Where a firm maintains shared service companies to provide services to affiliates, working capital should be maintained in those entities sufficient to permit those entities to continue to provide services for six months or through the period of stabilization as required in the firm's U.S. resolution strategy.

Costs related to third-party vendors and inter-affiliate services should be captured through the working capital element of the MOL estimate (RLEN).

Q2. When does the six month working capital requirement period begin?

A2. The measurement of the six month working capital expectation begins upon the bankruptcy filing of the U.S. IHC. The expectation for maintaining the working capital is effective upon the July 2018 submission.

OPS SS 3. Not Consolidated

OPS SS 4. Not Consolidated

Operations: Payments, Clearing and Settlement

To the extent relevant, the PCS FAQs have been consolidated into the updated section of the Proposed Guidance.

Legal Entity Rationalization and Separability

LER 1. Data Room

Q. What information should be in the data room?

A. The Proposed Guidance addresses the data room in the section regarding Legal Entity Rationalization and Separability. The data room should contain the necessary information on discrete sales options to facilitate buyer due diligence. Including only a table of contents of information that could be provided when needed would not be sufficient.

Q2. Are firms expected to include in a data room described in the Proposed Guidance lists of individual employee names and compensation levels?

A2. The firm should include the necessary information to facilitate buyer due diligence. In the circumstance where employee information would be important to buyer due diligence the firm should demonstrate the capability to provide such information in a timely manner. For individual employee names and compensation, the data room may include a representative sample and may have personally identifiable information redacted.

LER 2. Legal Entity Rationalization Criteria

Q. Is it acceptable to take into account business-related criteria, in addition to the resolution requirements, so that the LER Criteria can be used for both resolution planning and business operations purposes?

A. Yes, LER criteria may incorporate both business and resolution considerations. In determining the best alignment of legal entities and business lines to improve the firm's resolvability under different market conditions, business considerations should not be prioritized over resolution needs.

LER 3. Creation of Additional Legal Entities

Q. Is the addition of legal entities acceptable, so long as it is consistent with the LER criteria?

A. Yes.

LER 4. Clean Funding Pathways

Q1. Can you provide additional context around what is meant by clean lines of ownership and clean funding pathways in the legal entity rationalization criteria? Additionally, what types of funding are covered by the requirements?

A1. The funding pathways between the foreign parent, U.S. IHC, and U.S. IHC subsidiaries should minimize uncertainty in the provision of funds and facilitate recapitalization. Also, the complexity of ownership should not impede the flow of funding to a U.S. non-branch material entity under the firm's U.S. resolution strategy. Potential sources of additional complexity could include, for example, multiple intermediate holding companies, tenor mismatches, or complicated ownership structures (including those involving multiple jurisdictions or fractional ownerships). Ownership should be as clean and simple as practicable, supporting the U.S. strategy and actionable sales, transfers, or wind-downs under varying market conditions. The clean funding pathways expectation applies to all funding provided to a U.S. non-branch material entity regardless of type and should not be viewed solely to apply to internal TLAC.

Q2. The Proposed Guidance regarding legal entity rationalization criteria discusses ''clean lines of ownership'' and ''clean funding pathways.'' Does this statement mean that firms' legal entity rationalization criteria should require funding pathways and recapitalization to always follow lines of ownership?

A2. No. However, the firm should identify and address or mitigate any legal, regulatory, financial, operational, and other factors that could complicate the recapitalization and/or liquidity support of U.S. non-branch material entities.

LER 5. Separability Options Information

Q. How should a firm approach inclusion of legal risk assessments and other buyer due diligence information into separability options?

A. The legal assessment should consider both buyer and seller legal aspects that could impede the timely or successful execution of the divestiture option. Where impediments are identified, mitigation strategies should be developed.

LER 6. Market Conditions

Q. What is meant by the phrase ''under different market conditions'' in the Legal Entity Rationalization and Separability section of the Proposed Guidance?

A. The phrase ''under different market conditions'' is meant to ensure that a firm has a menu of divestiture options from which at least some could be executed under different market stresses.

LER 7. Application of Legal Entity Rationalization Criteria

Q1. Which legal entities should be covered under the LER framework?

A1. The scope of a firm's LER criteria should apply to the entire U.S. operations.

Q2. To the extent a firm has a large number of similar U.S. non-material entities (such as single-purpose entities formed for Community Reinvestment Act purposes), may a firm apply its legal entity rationalization criteria to these entities as a group, rather than at the individual entity level?

A2. Yes.

LER 8. Application of LER Criteria.

Q. Under the Proposed Guidance, is there an expectation that the LER criteria be applied to the legal structure outside of the U.S. operations (e.g., outside of the U.S. IHC or U.S. branch)?

A. The LER criteria serve to govern the corporate structure and arrangements between U.S. subsidiaries and U.S. branches in a manner that facilitates the resolvability of U.S. operations. The Proposed Guidance is not intended to govern the corporate structure in jurisdictions outside the U.S.

The application of the LER criteria should, among other things, ensure that the allocation of activities across the firm's U.S. branches and U.S. non-branch material entities support the firm's U.S. resolution strategy and minimize risk to U.S. financial stability in the event of resolution.

Moreover, LER works with other components to improve resolvability. For example, with regard to shared services the firm should identify all shared services that support identified critical operations, maintain a mapping of how/where these services support core business lines and identified critical operations, and include this mapping into the legal rationalization criteria and implementation efforts.

Derivatives and Trading Activities

To the extent relevant, the derivatives and trading FAQs have been consolidated into the updated section of the Proposed Guidance.

Legal

LEG 1. Support Within the United States

Q. Could the Agencies clarify what further legal analysis would be expected regarding the impact of potential state law and bankruptcy law challenges and mitigants to the planned provision of Support?

A. The firms should address developments from the firm's own analysis of potential legal challenges regarding the Support and should also address any additional potential legal challenges identified by the Agencies in the Support within the United States section of the Proposed Guidance. A legal analysis should include a detailed discussion of the relevant facts, legal challenges, and Federal or State law and precedent. The analysis also should evaluate in detail the legal challenges identified in the Support within the United States section of the Proposed Guidance, any other legal challenges identified by the firm, and the efficacy of potential mitigants to those challenges. Firms should identify each factual assumption underlying their legal analyses and discuss how the analyses and mitigants would change if the assumption were not to hold. Moreover, the analysis need not take the form of a legal opinion.

LEG 2. Contractually Binding Mechanisms

The Proposed Guidance states that the legal analysis described under the heading ''Support Within the United States'' should include mitigants to the potential challenges to the planned Support and that the plan should identify the mitigant(s) to such challenges that the firm considers most effective. The Proposed Guidance does not specifically reference consideration of a contractually binding mechanism. However, the following questions and answers may be useful to a firm that chooses to consider a contractually binding mechanism as a mitigant to the potential challenges to the planned Support.

Q1. Do the Agencies have any preference as to whether capital is down-streamed to key subsidiaries (including an IDI subsidiary) in the form of capital contributions vs. forgiveness of debt?

A1. No. The Agencies do not have a preference as to the form of capital contribution or liquidity support.

Q2. Should a contractually binding mechanism relate to the provision of capital or liquidity? What classes of assets would be deemed to provide capital vs. liquidity?

A2. Contractually binding mechanism is a generic term and includes the down-streaming of capital and/or liquidity as contemplated by the U.S. resolution strategy. Furthermore, it is up to the firm, as informed by any relevant guidance of the Agencies, to identify what assets would satisfy a U.S. affiliate's need for capital and/or liquidity.

Q3. Is there a minimum acceptable duration for a contractually binding mechanism? Would an ''evergreen'' arrangement, renewable on a periodic basis (and with notice to the Agencies), be acceptable?

A3. To the extent a firm utilizes a contractually binding mechanism, such mechanism, including its duration, should be appropriate for the firm's U.S. resolution strategy, including adequately addressing relevant financial, operational, and legal requirements and challenges.

Q4. Not consolidated.

Q5. Not consolidated.

Q6. The firm may need to amend its contractually binding mechanism from time to time resulting potentially from changes in relevant law, new or different regulatory expectations, etc. Is a firm able to do this as long as there is no undue risk to the enforceability (e.g., no signs of financial stress sufficient to unduly threaten the agreement's enforceability as a result of fraudulent transfer)?

A6. Yes, however the Agencies should be informed of the proposed duration of the agreement, as well as any terms and conditions on renewal and/or amendment. Any amendments should be identified and discussed as part of the firm's next U.S. resolution plan submission.

Q7. Not consolidated.

Q8. Should firms include a formal regulatory trigger by which the Agencies can directly trigger a contractually binding mechanism?

A8. No

General

None of the general FAQs were consolidated.

By order of the Board of Governors of the Federal Reserve System, March 11, 2020.

Margaret McCloskey Shanks,

Deputy Secretary of the Board.

Federal Deposit Insurance Corporation.

By order of the Board of Directors.

Dated at Washington, DC, on March 5, 2020.

Annmarie H. Boyd,

Assistant Executive Secretary.

[FR Doc. 2020–05513 Filed 3–17–20; 8:45 am]

BILLING CODE 6210–01–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 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 indicated. The applications will also be available for inspection at the offices of the Board of Governors. 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 and Constitution Avenue NW, Washington, DC 20551–0001, not later than April 1, 2020.

A. Federal Reserve Bank of San Francisco (Gerald C. Tsai, Director, Applications and Enforcement) 101 Market Street, San Francisco, California 94105–1579:

1. *The Rahman Family Trust Dated August 7, 1997, Altadena, California, Yahia Abdul Rahman and Madga Rahman, Trustees, both of Altadena, California; American Finance House Lariba, Whittier, California; Maie St. John, Los Angeles, California; Richard St. John, Los Angeles, California; and Marwa Abdul Rahman, Altadena, California;* to retain voting shares of Greater Pacific Bancshares, and thereby indirectly retain shares of Bank of Whittier, National Association, both of Whittier, California.

2. *Sang Young Lee and Chun Young Lee, both of La Canada, California, and Lee's Gold & Diamond Import, Inc., Los Angeles, California;* to acquire the voting shares of PCB Bancorp and thereby indirectly acquire shares of Pacific City Bank, both of Los Angeles, California.

Board of Governors of the Federal Reserve System, March 12, 2020.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2020–05535 Filed 3–17–20; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The 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 indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th and Constitution Avenue NW, Washington, DC 20551–0001, not later than April 16, 2020.

A. Federal Reserve Bank of Atlanta (Kathryn Haney, Assistant Vice President) 1000 Peachtree Street NE, Atlanta, Georgia 30309. Comments can also be sent electronically to *Applications.Comments@atl.frb.org:*

1. *CapStar Financial Holdings, Inc., Nashville, Tennessee;* to merge with FCB Corporation, Manchester, Tennessee, and thereby indirectly acquire First National Bank of Manchester, Manchester, Tennessee, and The Bank of Waynesboro, Waynesboro, Tennessee.

Board of Governors of the Federal Reserve System, March 12, 2020.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2020–05534 Filed 3–17–20; 8:45 am]

BILLING CODE P

FEDERAL RETIREMENT THRIFT INVESTMENT

Board Member Meeting

77 K Street NE, 10th Floor, Washington, DC 20002

March 23, 2020, 10 a.m., Telephonic

Open Session

1. Approval of the Minutes of the February 24, 2020 Board Meeting
2. Monthly Reports
   (a) Participant Activity Report
   (b) Legislative Report
   (c) Investment Performance
3. Quarterly Report: Vendor Risk Management Update
4. OERM Annual Report
5. Enterprise Risk Management Update
6. 5 Year Lifecycle Funds Project Update
7. Lifecycle Funds Study

Contact Person for More Information: Kimberly Weaver, Director, Office of External Affairs, (202) 942–1640.

Dated: March 12, 2020.

Megan Grumbine,

General Counsel, Federal Retirement Thrift Investment Board.

[FR Doc. 2020–05616 Filed 3–17–20; 8:45 am]

BILLING CODE 6760–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Request

AGENCY: Agency for Healthcare Research and Quality (AHRQ), Department of Health and Human Services (HHS).

ACTION: Request for information (RFI).

SUMMARY: For the ''*Opioid Management in Older Adults*'' project, AHRQ is seeking to identify innovative approaches to managing opioid medications for chronic pain that are particularly relevant for *older adults.* Use of long-term opioid therapy in older adults can be especially problematic because of increased risks such as delirium, falls, and dementia.

DATES: Information must be received by April 25, 2020.

ADDRESSES: Written comments should be submitted by email to: *Opioids_OlderAdults@abtassoc.com.*

FOR FURTHER INFORMATION CONTACT: Parivash Nourjah, *Parivash.nourjah@ahrq.gov,* or 301–427–1106.

SUPPLEMENTARY INFORMATION: The United States is in the midst of an unprecedented opioid epidemic that is affecting people from all walks of life. Regulators and policy makers have initiated many activities to curb the epidemic, but relatively little attention has been paid to the growing toll of opioid use, opioid misuse and opioid use disorder (OUD) among older adults.

The opioid crisis in older adults is strongly related to challenges in prescription opioid management in this population. Older adults have a high prevalence of chronic pain and are especially vulnerable to suffering adverse events from opioid use, making safe prescribing more challenging even when opioids are an appropriate therapeutic choice. Identifying adverse effects due to opioid use, misuse or abuse is complicated further by factors such as co-occurring medical disorders that can mimic the effects of opioid use. There is also a risk of attributing clinical findings in older adults (*e.g.* personality changes, falls/balance problems, difficulty sleeping, and heart problems) to other conditions that are also common with age. If adverse events due to opioid prescriptions are identified, finding appropriate alternatives for pain management can be challenging if other pharmacologic options (such as NSAIDS) are contraindicated or mobility issues limit access to other therapeutic options.

Diagnosis of substance use disorders is also more complicated in this population. Clinicians may not associate drug misuse or addiction with older adults or they may be inadequately trained in identification and treatment of opioid misuse and OUD among older adults, and hence may not monitor for the signs of opioid use disorder in this population.

Successfully optimizing the prescribing and use of opioids in older adults will require addressing the issue at many points along the care continuum where older adults may need additional attention or a different approach. AHRQ wants to identify specific tools, strategies and approaches to opioid management in older adults throughout the breadth of the care delivery continuum, from avoiding opioid initiation to screening for opioid misuse and opioid use disorder, as well as approaches to opioid tapering in older adults.

AHRQ is interested in all innovative approaches that address the opioid management concerns in older adults listed above, but respondents are welcome to address as many or as few as they choose and to address additional areas of interest not listed.

Strategies and approaches could come from a variety of health care settings including, but not limited to, primary care and other ambulatory care clinics, emergency departments, home health care organizations, skilled nursing care settings, and inpatient care. Other sources of these strategies might include health care payers, accountable care organizations, and organizations that

provide external quality improvement support. Some of the examples of the types of innovations we are looking for might be specific tools or workflows that support providers to assess the risk/benefit balance of opioids within a multidisciplinary approach in pain management; to optimize and monitor the opioid prescribing when appropriate, including tapering strategies; to screen and treat for opioid misuse or opioid use disorder; or to involve family or other caregivers of an older adult in conversations about opioid safety. Descriptions of strategies or approaches should include the setting where it is deployed and the type of patient population served.

This RFI is for planning purposes only and should not be construed as a policy, solicitation for applications, or as an obligation on the part of the Government to provide support for any ideas in response to it. AHRQ will use the information submitted in response to this RFI at its discretion, and will not provide comments to any respondent's submission. However, responses to the RFI may be reflected in future solicitation(s) or policies. Respondents are advised that the Government is under no obligation to acknowledge receipt of the information received or provide feedback to respondents with respect to any information submitted. No proprietary, classified, confidential or sensitive information should be included in your response. The Government reserves the right to use any non-proprietary technical information in any resultant solicitation(s). The contents of all submissions will be made available to the public upon request. Submitted materials must be publicly available or able to be made public.

Dated: March 12, 2020.

Virginia Mackay-Smith,

Associate Director, Office of the Director, AHRQ.

[FR Doc. 2020–05612 Filed 3–17–20; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Meeting of the National Advisory Council for Healthcare Research and Quality

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Notice of change to public meeting.

SUMMARY: In response to recently issued OPM guidance to agencies on reducing non-essential travel, this notice announces a change to a meeting of the National Advisory Council for Healthcare Research and Quality.

DATES: The meeting will be held on Thursday, March 26, 2020, from 12:30 p.m. to 3:30 p.m.

ADDRESSES: The meeting will now be held virtually (via WebEx).

FOR FURTHER INFORMATION CONTACT: Jaime Zimmerman, Designated Management Official, at the Agency for Healthcare Research and Quality, 5600 Fishers Lane, Mail Stop 06E37A, Rockville, Maryland, 20857, (301) 427–1456. For press-related information, please contact Bruce Seeman at (301) 427–1998 or *Bruce.Seeman@AHRQ.hhs.gov.*

Closed captioning will be provided during the WebEx. If another reasonable accommodation for a disability is needed, please contact the Food and Drug Administration (FDA) Office of Equal Employment Opportunity and Diversity Management on (301) 827–4840, no later than Thursday, March 19, 2020. The agenda, roster, and minutes will be available from Ms. Heather Phelps, Committee Management Officer, Agency for Healthcare Research and Quality, 5600 Fishers Lane, Rockville, Maryland 20857. Ms. Phelps' phone number is (301) 427–1128.

SUPPLEMENTARY INFORMATION:

I. Purpose

In accordance with section 10(a) of the Federal Advisory Committee Act, 5 U.S.C. App., this notice announces a meeting of the National Advisory Council for Healthcare Research and Quality (the Council). The Council is authorized by Section 941 of the Public Health Service Act, 42 U.S.C. 299c. In accordance with its statutory mandate, the Council is to advise the Secretary of the Department of Health and Human Services and the Director of AHRQ on matters related to AHRQ's conduct of its mission including providing guidance on (A) priorities for health care research, (B) the field of health care research including training needs and information dissemination on health care quality and (C) the role of the Agency in light of private sector activity and opportunities for public private partnerships. The Council is composed of members of the public, appointed by the Secretary, and Federal ex-officio members specified in the authorizing legislation.

II. Agenda

On Thursday, March 26, 2020, the Council meeting will convene at 12:30 p.m., with the call to order by the Council Chair and approval of previous Council summary notes. The meeting is open to the public and will be available via webcast at *www.webconferences.com/ahrq.* The meeting will begin with an update on AHRQ's recent accomplishments and budget. The agenda will also include a discussion about 21st Century Care and AHRQ Data and Analytics Initiatives, including Synthetic Data. The meeting will adjourn at 3:30 p.m. For information on accessing the WebEx, as well as other meeting details, including information on how to make a public comment, please go to *https://www.ahrq.gov/news/events/nac/.* The final agenda will be available on the AHRQ website no later than Thursday, March 19, 2020.

Dated: March 12, 2020.

Virginia L. Mackay-Smith,

Associate Director.

[FR Doc. 2020–05563 Filed 3–17–20; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB #0970–0509]

Expedited OMB Review and Public Comment: Information Collection Activity; Medical Complaint Form, Contact Investigation Form: Non-TB Illness, and Contact Investigation Form: Active/Suspect TB

AGENCY: Office of Refugee Resettlement; Administration for Children and Families; Department of Health and Human Services.

ACTION: Request for public comment.

SUMMARY: The Office of Refugee Resettlement (ORR), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is requesting expedited review of an information collection request from the Office of Management and Budget (OMB) and inviting public comments on the proposed revisions. The request consists of the addition of questions to the Medical Complaint Form to track instances of COVID–19.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and

Families is soliciting public comment on the specific aspects of the information collection described in this notice.

ADDRESSES: Copies of the proposed collection of information can be obtained by emailing *infocollection@acf.hhs.gov.* All requests should identify the title of the information collection. Written comments and recommendations for the proposed information collection should be sent directly to the following: Administration for Children and Families, Paperwork Reduction Project, Email: *infocollection@afc.hhs.gov,* Attn: Desk Officer for the Administration for Children and Families.

SUPPLEMENTARY INFORMATION:

Description: ACF is requesting that OMB grant a 180-day approval for this request under procedures for expedited processing. A request for review under normal procedures will be submitted within 180 days of the approval for this request. Any edits resulting from public comment will be incorporated into the submission under normal procedures.

The Medical Complaint form is to be updated in response to the COVID–19 outbreak. Two fields were added to capture the COVID–19 diagnosis and related public health interventions.

Respondents: ORR Grantee Staff.

Annual Burden Estimates: The following burden estimates were previously approved by OMB for data collection under OMB #0970–0509. The addition of this data element does not increase reporting or record keeping burden.

ESTIMATED OPPORTUNITY BURDEN FOR RESPONDENTS

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Medical Complaint Form	120	836	0.13	13,042

Total: 13,042.

ESTIMATED RECORDKEEPING BURDEN FOR RESPONDENTS

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Medical Complaint Form	120	836	0.08	8,026

Total: 8,026.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 6 U.S.C. 279: Exhibit 1, part A.2 of the Flores Settlement Agreement (*Jenny Lisette Flores, et al.,* v. *Janet Reno, Attorney General of the United States, et al.,* Case No. CV 85–4544–RJK [C.D. Cal. 1996])

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2020–05628 Filed 3–17–20; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB #0970–0466]

Expedited OMB Review and Public Comment: Information Collection Activity; Initial Medical Exam Form and Initial Dental Exam Form

AGENCY: Office of Refugee Resettlement; Administration for Children and Families; Department of Health and Human Services.

ACTION: Request for public comment.

SUMMARY: The Office of Refugee Resettlement (ORR), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is requesting expedited review of an information collection request from the Office of Management and Budget (OMB) and inviting public comments on the proposed revisions. The request consists of the addition of questions to the Initial Medical Exam Form to track instances of COVID–19.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described in this notice.

ADDRESSES: Copies of the proposed collection of information can be obtained by emailing *infocollection@acf.hhs.gov.* All requests should identify the title of the information collection. Written comments and recommendations for the proposed information collection should be sent directly to the following: Administration for Children and Families, Paperwork Reduction Project, Email: *infocollection@acf.hhs.gov*, Attn: Desk Officer for the Administration for Children and Families.

SUPPLEMENTARY INFORMATION:

Description: ACF is requesting that OMB grant a 180-day approval for this request under procedures for expedited processing. A request for review under normal procedures will be submitted within 180 days of the approval for this request. Any edits resulting from public comment will be incorporated into the submission under normal procedures. The Initial Medical Exam Form is to be updated in response to the COVID–19 outbreak. Three fields were added to capture travel history, COVID–19 diagnosis, and related public health interventions.

Respondents: ORR Grantee Staff.

Annual Burden Estimates: The following burden estimates were previously approved by OMB for data collection under OMB #0970–0466. The addition of these data elements does not increase reporting or record keeping burden.

ESTIMATED OPPORTUNITY BURDEN FOR RESPONDENTS

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Initial Medical Exam Form (including Appendix A: Supplemental TB Screening Form)	150	297	0.22	9,801

Total: 9,801.

ESTIMATED RECORDKEEPING BURDEN FOR RESPONDENTS

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Initial Medical Exam Form (including Appendix A: Supplemental TB Screening Form)	150	297	0.08	3,564

Total: 3,564.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 6 U.S.C. 279: Exhibit 1, part A.2 of the Flores Settlement Agreement (*Jenny Lisette Flores, et al.,* v. *Janet Reno, Attorney General of the United States, et al.,* Case No. CV 85–4544–RJK [C.D. Cal. 1996])

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2020–05624 Filed 3–17–20; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–0567]

Restricted Delivery Systems: Flow Restrictors for Oral Liquid Drug Products; 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 ''Restricted Delivery Systems: Flow Restrictors for Oral Liquid Drug Products.'' This guidance provides recommendations regarding the use of restricted delivery systems to limit unintentional ingestion of oral liquid drug products (*e.g.,* oral solution, oral suspension) by children. The recommendations in this guidance apply broadly to oral liquid drug and biological products. FDA's recommendations are intended to minimize the potential for harm due to unintentional ingestions.

DATES: Submit either electronic or written comments on the draft guidance by May 18, 2020 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 Division of Dockets Management, 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–0567 for ''Restricted Delivery Systems: Flow Restrictors for Oral Liquid Drug Products.'' 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.

• 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.

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 draft 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; or the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, 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 draft guidance document.

FOR FURTHER INFORMATION CONTACT: Rhiannon Leutner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD, 20993–0002, 240–402–5998, 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, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Restricted Delivery Systems: Flow Restrictors for Oral Liquid Drug Products.'' This guidance provides recommendations regarding the use of restricted delivery systems to limit unintentional ingestion of oral liquid drug products (*e.g.,* oral solution, oral suspension) by children. The recommendations in this guidance apply broadly to oral liquid drug and biological products.

A restricted delivery system, according to USP General Chapter <659> Packaging and Storage Requirements, is a packaging system that is designed or constructed to restrict (control) the amount of drug product that is delivered. Manufacturers should consider a restricted delivery system, such as a flow restrictor, as an additional measure to further reduce the risk that unintended ingestions of oral liquid drug products pose to public health. FDA is issuing this guidance to describe the elements that should be considered in developing restricted delivery systems for oral liquid drug products.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Restricted Delivery Systems: Flow Restrictors for Oral Liquid Drug Products.'' 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. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 314, including the submission of new drug and abbreviated new drug applications and supplements, have been approved under OMB control number 0910–0001; the collections of information in 21 CFR part 601, including the submission of biologics license applications and supplements, have been approved under OMB control number 0910–0338; the collections of information in 21 CFR 201.66 for format and content requirements for over-the-counter drug product labeling have been approved under OMB control number 0910–0340; and the collections of information in 21 CFR 201.56 and 201.57 for format and content requirements for human prescription drug and biological product labeling have been approved under OMB control number 0910–0572.

III. Electronic Access

Persons with access to the internet may obtain the draft 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/biologics-guidances*, or *https://www.regulations.gov.*

Dated: March 13, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–05617 Filed 3–17–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3731]

Michael P. Casey: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Michael P. Casey for a period of 5 years from importing articles of food or offering such articles for importation into the United States. FDA bases this order on a finding that Mr. Casey was convicted, as defined in the FD&C Act, of a felony count under Federal law for conduct relating to the importation into the United States of an article of food. Mr. Casey was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of November 4, 2019 (30 days after receipt of the notice), Mr. Casey has not responded. Mr. Casey's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this matter.

DATES: This order is applicable March 18, 2020.

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Enforcement, Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240–402–8743, or at *debarments@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(1)(C) of the FD&C Act (21 U.S.C. 335a(b)(1)(C)) permits FDA to debar an individual from importing an article of food or offering such an article for import into the United States if FDA finds, as required by section 306(b)(3)(A) of the FD&C Act, that the individual has been convicted of a felony for conduct relating to the importation into the United States of any food.

On July 18, 2019, Mr. Casey was convicted as defined in section 306(*l*)(1)(B) of the FD&C Act, in the United States District Court for the Eastern District of Virginia, when the court accepted his plea of guilty and entered judgment against him for the offense of conspiracy to violate the Lacey Act in violation of 18 U.S.C. 371 and 16 U.S.C. 3372(d) and 3373(d)(3)(A)(i).

FDA's finding that the debarment is appropriate is based on the felony conviction referenced herein. The factual basis for this conviction is as follows: As contained in the Stipulation of Facts incorporated into Mr. Casey's Plea Agreement, filed on July 18, 2019, from on or about 2010 to June 2015, while serving as the Vice President for Marketing and Operations of Casey's Seafood, Inc. (''the Company''), Mr. Casey and the Company regularly purchased foreign crab meat from a variety of sources and from a number of different countries. Mr. Casey also purchased foreign crab meat that had been recalled, returned, or that was approaching or beyond its posted ''best used by'' dates. Mr. Casey knew that company employees were directed to unpack the foreign crab meat from containers and re-pack the crab meat into company containers, all of which were labeled ''Product of USA.'' During that time period, employees routinely emptied foreign crab meat onto tables, comingling crab meat from different sources, and then re-packaged the crab meat into company containers, all of which were labeled ''Product of USA.'' From on or about July 1, 2012, and continuing until June 17, 2015, Mr. Casey aided and abetted James R. Casey, the President of the Company, in processing approximately 90,868 pounds of crab. From on or about July 1, 2012, and continuing until June 17, 2015, Mr. Casey aided and abetted the President of the Company in selling 367, 765 pounds of crab meat falsely labeled ''Product of USA'' with a total wholesale value of approximately $4, 324, 916.

As a result of this conviction, FDA sent Mr. Casey by certified mail on September 30, 2019, a notice proposing to debar him for a period of 5 years from importing articles of food or offering such articles for import into the United States. The proposal was based on a finding under section 306(b)(1)(C) of the FD&C Act that Mr. Casey's felony conviction of conspiracy to violate the Lacey Act in violation of 18 U.S.C. 371 and 16 U.S.C. 3372(d) and 3373(d)(3)(A)(i) constitutes conduct relating to the importation into the United States of an article of food because the offense he committed involved falsely labeling crab meat that was imported from a number of foreign countries as ''Product of USA.''

The proposal was also based on a determination, after consideration of the relevant factors set forth in section 306(c)(3) of the FD&C Act, that Mr. Casey should be subject to a 5-year period of debarment. The proposal also offered Mr. Casey an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Casey failed to respond within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(b)(1)(C) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Casey has been convicted of a felony count under Federal law for conduct relating to the importation into the United States of an article of food and that he is subject to a 5-year period of debarment.

As a result of the foregoing finding, Mr. Casey is debarred for a period of 5 years from importing articles of food or offering such articles for import into the United States, effective (see **DATES**). Pursuant to section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of an article of food by, with the assistance of, or at the direction of Mr. Casey is a prohibited act.

Any application by Mr. Casey for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2019–N–3731 and sent to the Dockets Management Staff (see **ADDRESSSES**). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20.

Publicly available submissions will be placed in the docket, and will be viewable at *http://www.regulations.gov* or at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 12, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–05581 Filed 3–17–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–4046]

Charles Jeffrey Edwards: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) permanently debarring Charles Jeffrey Edwards from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Mr. Edwards was convicted, as defined in the FD&C Act, of two felony counts under federal law for conduct that relates to the regulation of a drug product under the FD&C Act. Mr. Edwards was given notice of the proposed permanent debarment and was given an opportunity to request a hearing within the timeframe prescribed by regulation to show why he should not be debarred. As of November 15, 2019 (30 days after receipt of the notice), Mr. Edwards had not responded. Mr. Edwards's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is applicable March 18, 2020.

ADDRESSES: Submit applications for special termination of debarment to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa (ELEM–4029) Division of Enforcement, Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240–402–8743 or at *debarments@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(B) of the FD&C Act (21 U.S.C. 335a(a)(2)(B)) requires debarment of an individual from providing services in any capacity to a person that has an approved or pending drug product application if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the regulation of any drug product under the FD&C Act. On July 20, 2018, Mr. Edwards was convicted as defined in section 306(*l*)(1)(A) of the FD&C Act when judgment was entered against Mr. Edwards in the U.S. District Court for the Middle District of Tennessee, Nashville Division, after his plea of guilty, to one count of mail fraud in violation of 18 U.S.C. 1341 and one count of money laundering in violation of 18 U.S.C. 1957.

The factual basis for these convictions is as follows: as contained in Counts 2 and 27 of the Indictment, filed on January 17, 2013, to which Mr. Edwards pleaded guilty, from December 2006 through August 2009, Mr. Edwards, along with others, through Cumberland Distribution, Inc. (Cumberland), a company Mr. Edwards co-owned, was engaged in wholesale distribution of prescription drugs as defined by section 505(e) of the FD&C Act (21 U.S.C. 355(e)). Cumberland purchased millions of dollars of prescription drugs from unlicensed drug suppliers who were not authorized to distribute drugs under section 503 of the FD&C Act (21 U.S.C. 353). Mr. Edwards knew that these unlicensed suppliers often procured drugs from street level drug diverters who had obtained the drugs from persons with legitimate prescriptions. On many occasions, Mr. Edwards had drugs shipped to his shell companies, which Mr. Edwards used as passthroughs to create the appearance that his company was purchasing drugs from licensed suppliers, when in fact Mr. Edwards was purchasing drugs from unlicensed suppliers. Afterwards, Mr. Edwards had these drugs shipped to Cumberland's Nashville warehouse where they were repackaged and shipped to independent pharmacies around the country. Mr. Edwards also directed Cumberland employees to create false pedigree documents to make it appear that the diverted drugs were purchased from authorized sellers. The diverted drugs included drugs used to combat human immunodeficiency virus/acquired immunodeficiency syndrome; antipsychotic medications; antidepressants; blood pressure medications; diabetes medications, among others. Through the course of this scheme, Mr. Edwards' company had gross proceeds of approximately $58,984,912. Mr. Edwards and two others obtained profits of approximately $14,689,782.

As a result of these convictions, FDA sent Mr. Edwards by certified mail on October 9, 2019, a notice proposing to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(B) of the FD&C Act, that Mr. Edwards was convicted of two felonies under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. The proposal also offered Mr. Edwards an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted an election not to use the opportunity for a hearing and a waiver of any contentions concerning this action. Mr. Edwards received the proposal on October 16, 2019. Mr. Edwards did not request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(a)(2)(B) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Edwards has been convicted of two felonies under Federal law for conduct otherwise relating to the regulation of a drug product under the FD&C Act.

As a result of the foregoing finding, Mr. Edwards is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application, effective (see **DATES**) (see sections 306(a)(2)(B) and 306(c)(2)(A)(ii) of the FD&C Act). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Mr. Edwards, in any capacity during his debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Mr. Edwards provides services in any capacity to a person with an approved or pending drug product application during his period of debarment he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug applications from Mr. Edwards during his period of debarment, other than in connection with an audit under section 306 of the FD&C Act (section 306(c)(1)(B) of the FD&C Act). Note that, for purposes of section 306 of the FD&C Act, a ''drug product'' is defined as a ''drug subject to regulation under section 505, 512, or 802 of this Act [(21 U.S.C. 355, 360b, 382)] or under section 351 of the Public Health Service Act [(42 U.S.C. 262)]''

(section 201(dd) of the FD&C Act (21 U.S.C. 321(dd)).

Any application by Mr. Edwards for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA–2019–N–4046 and sent to the Dockets Management Staff (see **ADDRESSES**). All such submissions are to be filed in four copies (21 CFR 10.20(a)). The public availability of information in these submissions is governed by 21 CFR 10.20.

Publicly available submissions may be seen in the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 12, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–05582 Filed 3–17–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Promoting the Rule of Law Through Improved Agency Guidance Documents

AGENCY: Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services has received an extension to the deadline to comply with Executive Order 13891: *Promoting the Rule of Law Through Improved Agency Guidance Documents.* Executive Order 13891, through Subsections (a) and (b), requires the establishment of a new guidance portal and the rescission of any guidance documents that are not included in it, respectively. The Office of Management and Budget (OMB), through its implementing memorandum (*https://www.whitehouse.gov/wp-content/uploads/2019/10/M-20-02-Guidance-Memo.pdf*), has determined the deadlines for these subsections to be February 28, 2020. OMB granted the Department of Health and Human Services an extension for subsections (a) and (b) on February 27, 2020. The Department will establish its guidance portal by August 31, 2020.

A full copy of the extension letter can be found on the HHS website at, *https://www.hhs.gov/regulations/index.html.*

FOR FURTHER INFORMATION CONTACT: Samuel Shipley, Office of the Executive Secretary, at *Guidance@hhs.gov* or (202) 690–5627.

Dated: March 12, 2020.

Ann C. Agnew,

Executive Secretary, Department of Health and Human Services.

[FR Doc. 2020–05647 Filed 3–17–20; 8:45 am]

BILLING CODE 4150–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; R13 Conference Grants.

Date: April 14, 2020.

Time: 8:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: NIH/NHLBI, Rockledge I, 6705 Rockledge Drive, Bethesda, MD 20814 (Virtual Meeting).

Contact Person: Michael P. Reilly, Ph.D., Scientific Review Officer, Office of Scientific Review, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Bethesda, MD 20892, 301–827–7975, *reillymp@nhlbi.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: March 13, 2020.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–05626 Filed 3–17–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, Fellowships: Physiology and Pathobiology of the Vascular and Hematological Systems, March 27, 2020 8:00 a.m. to March 27, 2020, 8:00 p.m., The William F. Bolger Center, 9600 Newbridge Drive, Potomac, MD 20854, which was published in the **Federal Register** on March 4, 2020, 85 FR 12799.

The meeting location is being held at the National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. The meeting date and time remains the same. The meeting is closed to the public.

Dated: March 13, 2020.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–05637 Filed 3–17–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel HHS–NIH–CDC–SBIR 2018–1 Phase II Topic 053: Effective Targeted Delivery of RNA-based Vaccines and Therapeutics.

Date: April 15, 2020.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of

Health, 5601 Fishers Lane, Room 3G22, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Inka I Sastalla, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G22, Rockville, MD 20852, (301) 761–6431, *inka.sastalla@nih.gov.*

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; HHS–NIH–CDC SBIR PHS 2018–1 Phase II Topic 052: High-Throughput Assay Platform for Quantifying Latent HIV Reservoirs.

Date: April 21, 2020.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G22, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Inka I Sastalla, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G22, Rockville, MD 20852, (301) 761–6431, *inka.sastalla@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: March 13, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–05630 Filed 3–17–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases: Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Clinical Trial Planning Grant (R34 Clinical Trial Not Allowed).

Date: April 21, 2020.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G53 Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Konrad Krzewski, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G53, Rockville, MD 20852, 240–747–7526, *konrad.krzewski@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: March 12, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–05627 Filed 3–17–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel, April 24, 2020, 8:00 a.m. to 5:00 p.m., National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Bethesda, MD 20817, which was published in the **Federal Register** on January 27, 2020, 85 FR 4673.

This meeting notice is amended to change the meeting dates, times, and format. The meeting will now be held as a teleconference on two days—April 23, 2020, 8:00 a.m. to April 24, 2020, 6:00 p.m. The meeting is closed to the public.

Dated: March 13, 2020.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–05645 Filed 3–17–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Institute Special Emphasis Panel, March 26, 2020, 8:00 a.m. to March 27, 2020, 7:00 p.m., Marriott Bethesda North Hotel & Conference Hotel, 5701 Marinelli Rd., Rockville, MD 20850 which was published in the **Federal Register** on January 30, 2020, 85 FR 5459.

This meeting notice is amended to change the meeting location, times, and format. The meeting will now be held on March 26, 2020, 8:00 a.m. to March 27, 2020, 4:00 p.m. as a teleconference at National Cancer Institute (NCI) Shady Grove, 9609 Medical Center Drive, Rockville, MD 20850. The meeting is closed to the public.

Dated: March 13, 2020.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–05641 Filed 3–17–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Heart, Lung, and Blood Institute Special Emphasis Panel, March 24, 2020, 08:00 a.m. to 05:00 p.m., Embassy Suites at Chevy Chase Pavilion, 4300 Military Road NW, Washington, DC 20015 which was published in the **Federal Register** on January 29, 2020, 85 FR 5221.

The NHLBI Special Emphasis Panel meeting is being amended due to a change in the meeting format. This one-day meeting to be held on March 24, 2020 will be a teleconference meeting. The meeting is closed to the public.

Dated: March 13, 2020.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–05625 Filed 3–17–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Institute Special Emphasis Panel, April 15, 3:00 p.m. to April 16, 2020, 6:00 p.m., Bethesda North Marriott Hotel & Conference Hotel, 5701 Marinelli Road, Rockville, MD 20850 which was published in the **Federal Register** on February 07, 2020, 85 FR 7317.

This meeting notice is amended to change the meeting location, time, and format. The meeting will be held on April 15, 2020, 11:00 a.m. to April 16, 2020, 7:00 p.m. as a teleconference at National Cancer Institute (NCI) Shady Grove, 9609 Medical Center Drive, Rockville, MD 20850. The meeting is closed to the public.

Dated: March 13, 2020.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–05640 Filed 3–17–20; 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 Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Pulmonary Diseases.

Date: March 31–April 1, 2020.

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 Dr., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Bradley Nuss, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4142, MSC 7814, Bethesda, MD 20892, 301–451–8754, *nussb@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(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: March 13, 2020.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–05639 Filed 3–17–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of Neurological Disorders and Stroke Special Emphasis Panel, March 19, 2020, 8:00 a.m. to March 20, 2020, 5:00 p.m., Canopy by Hilton, 940 Rose Avenue, North Bethesda, MD 20852 which was published in the **Federal Register** on February 20, 2020, 85FR9789.

This meeting notice is to change the meeting format from in-person to virtual. The meeting is closed to the public.

Dated: March 13, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–05634 Filed 3–17–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Institute Special Emphasis Panel, March 26, 2020, 8:00 a.m. to 6:00 p.m., Marriott Bethesda North Hotel & Conference Hotel, 5701 Marinelli Rd, Rockville, MD, 20850 which was published in the **Federal Register** on December 2, 2019, 84 FR 65990.

This meeting notice is amended to change the meeting location and format. The meeting will now be held on March 26, 2020, 8:00 a.m. to 6:00 p.m. as a teleconference at National Cancer Institute (NCI) Shady Grove, 9609 Medical Center Drive, Rockville, MD 20850. The meeting is closed to the public.

Dated: March 13, 2020.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–05642 Filed 3–17–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Board of Scientific Counselors, National Institute of Neurological Disorders and Stroke, March 22, 2020, 06:00 p.m. to March 24, 2020, 12:00 p.m., Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814 which was published in the **Federal Register** on November 15, 2019, 84 FR 62543.

The meeting notice is to change the meeting format to virtual instead of in person. The meeting is closed to the public.

Dated: March 13, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–05633 Filed 3–17–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases: Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material,

and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Microbiology, Infectious Diseases and AIDS Initial Review Group; Acquired Immunodeficiency Syndrome Research Review Committee AIDS Chartered Committee.

Date: April 15–16, 2020.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Robert C. Unfer, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3F40A, National Institutes of Health, NIAID, 5601 Fishers Lane, MSC 9834, Bethesda, MD 20892–9834, (240) 669–5035, *robert.unfer@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: March 12, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–05629 Filed 3–17–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse: Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Mechanism for Time-Sensitive Drug Abuse Research (R21 Clinical Trial Optional).

Date: March 30, 2020.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neurosciences Center Building, 6001 Executive Boulevard, Conference Room B1, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Susan O. McGuire, Ph.D., Scientific Review Officer, Office of Extramural Affairs, National Institute on Drug Abuse, National Institutes of Health, 6001 Executive Boulevard, Room 4245, Rockville, MD 20852, 301–435–1426, *mcguireso@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: March 12, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–05631 Filed 3–17–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel, April 3, 2020, 8:00 a.m. to 5:00 p.m., National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Conference Rooms B & C, Bethesda, MD 20817, which was published in the **Federal Register** on January 20, 2020, 85 FR 5458.

This meeting notice is amended to change the meeting dates, times, and format. The meeting will now be held as a teleconference on two days—April 2, 2020, 8:00 a.m. to April 3, 2020, 5:00 p.m. The meeting is closed to the public.

Dated: March 13, 2020.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–05644 Filed 3–17–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism, Initial Review Group Clinical, Treatment and Health Services Research Review Subcommittee.

Date: June 19, 2020.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: JW Marriott New Orleans, 3rd Floor, Suite 1, 614 Canal Street, New Orleans, LA 70130.

Contact Person: Luis Espinoza, Ph.D., Scientific Review Officer, Extramural Project Review Branch, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Room 2109, Bethesda, MD 20817, (301) 443–8599, *espinozala@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards., National Institutes of Health, HHS)

Dated: March 13, 2020.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–05643 Filed 3–17–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific

Review Special Emphasis Panel, Fellowships: Physiology and Pathobiology of the Vascular and Hematological Systems, March 27, 2020 10:00 a.m. to March 27, 2020, 2:00 p.m., The William F. Bolger Center, 9600 Newbridge Drive, Potomac, MD 20854, which was published in the **Federal Register** on March 04, 2020, 85 FR 12799.

The meeting location is being held at the National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. The meeting date and time remains the same.

Dated: March 13, 2020.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–05638 Filed 3–17–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute on Drug Abuse Special Emphasis Panel, March 26, 2020, 8:00 a.m. to 5:00 p.m., Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852, which was published in the **Federal Register** on February 28, 2020, 85 FR 11998.

This meeting is amended to change the meeting location and format. The meeting will now be held as a teleconference at the National Institutes of Health, Neurosciences Center Building, 6001 Executive Boulevard, Room 4236, Rockville, MD 20852. The meeting is closed to the public.

Dated: March 12, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–05632 Filed 3–17–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2020–0048]

National Offshore Safety Advisory Committee; Meeting Cancellation

AGENCY: U.S. Coast Guard, Department of Homeland Security.

ACTION: Notice of federal advisory committee meeting; cancellation.

SUMMARY: On February 6, 2020 (85 FR 25, Page 6962), the U.S. Coast Guard published a notice that announced a meeting of the National Offshore Safety Advisory Committee, which was scheduled to take place on March 24th and March 25th 2020. The Coast Guard is publishing this notice to announce that this federal advisory committee meeting has been cancelled and will be rescheduled at a later date. The rescheduled meetings will be announced in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Commander Myles Greenway, Designated Federal Officer of the National Offshore Safety Advisory Committee, Commandant (CG–OES–2), U.S. Coast Guard, 2703 Martin Luther King Jr. Avenue SE, Stop 7509, Washington, DC 20593–7509; telephone (202) 372–1410, fax (202) 372–8382 or email: *Myles.J.Greenway@uscg.mil,* or Mr. Patrick Clark, telephone (202) 372–1358, or email *patrick.w.clark@uscg.mil.*

Dated: March 11, 2020.

Jeffrey G. Lantz,

Director of Commercial Regulations and Standards.

[FR Doc. 2020–05599 Filed 3–17–20; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2019–0946]

Recertification of Prince William Sound Regional Citizens' Advisory Council

AGENCY: Coast Guard, DHS.

ACTION: Notice of recertification.

SUMMARY: The Coast Guard announces the recertification of the Prince William Sound Regional Citizens' Advisory Council (PWSRCAC) as an alternative voluntary advisory group for Prince William Sound, Alaska. This certification allows the PWSRCAC to monitor the activities of terminal facilities and crude oil tankers under an alternative composition, other than prescribed, Prince William Sound Program established by statute.

DATES: This recertification is effective for the period from March 2, 2020, through February 28, 2021.

FOR FURTHER INFORMATION CONTACT: For information about this document, call or email LT Ian McPhillips, Seventeenth Coast Guard District (dpi), by phone at (907) 463–2809 or email at *Ian.P.McPhillips@uscg.mil.*

SUPPLEMENTARY INFORMATION:

Background and Purpose

The Coast Guard published guidelines on December 31, 1992 (57 FR 62600), to assist groups seeking recertification under the Oil Terminal and Oil Tanker Environmental Oversight and Monitoring Act of 1990 (33 U.S.C. 2732) (the Act). The Coast Guard issued a policy statement on July 7, 1993 (58 FR 36504), to clarify the factors that the Coast Guard would be considering in making its determination as to whether advisory groups should be certified in accordance with the Act, and the procedures which the Coast Guard would follow in meeting its certification responsibilities under the Act. Most recently, on September 16, 2002 (67 FR 58440), the Coast Guard changed its policy on recertification procedures for regional citizen's advisory council by requiring applicants to provide comprehensive information every three years. For the two years in between, applicants only submit information describing substantive changes to the information provided at the last triennial recertification. This is the year in the triennial cycle in which PWSRCAC provided comprehensive information on its application for recertification. The Coast Guard solicited public comments on PWSRCAC recertification through a Notice; Request for comments published on December 26, 2019, titled ''Application for Recertification of Prince William Sound Regional Citizens' Advisory Council'' (82 FR 29572).

The Alyeska Pipeline Service Company pays the PWSRCAC $3.7 million annually in the form of a long-term contract. In return for this funding, the PWSRCAC must annually show that it ''fosters the goals and purposes'' of OPA 90 and is ''broadly representative of the communities and interests in the vicinity of the terminal facilities and Prince William Sound.'' The PWSRCAC is an independent, nonprofit organization founded in 1989. Though it receives federal oversight like many independent, nonprofit organizations, it is not a federal agency. The PWSRCAC is a local organization that predates the passage of OPA 90. The existence of the PWSRCAC was specifically recognized in OPA 90 where it is defined as an ''alternative voluntary advisory group.'' Alyeska Pipeline Service Company funds the PWSRCAC, and the Coast Guard ensures the PWSRCAC operates in a fashion that is broadly consistent with OPA 90.

Discussion of Comments

On December 26, 2019, the Coast Guard published a Notice; Request for comments titled ''Application for Recertification of Prince William Sound Regional Citizens' Advisory Council'' in the **Federal Register** (82 FR 29572). We received 69 comments, all in support of the PWSRCAC recertification. No public meeting was requested. The comments consistently cited PWSRCAC's broad representation of the respective communities' interest, appropriate actions to keep the public informed, improvements to both spill response preparation and spill prevention, and oil spill industry monitoring efforts that combat complacency—as intended by the Act.

Recertification

By letter dated February 25, 2020, the Commander, Seventeenth Coast Guard District, certified that the PWSRCAC qualifies as an alternative voluntary advisory group under 33 U.S.C. 2732(o). This recertification terminates on February 28, 2021.

Dated: February 25, 2020.

Matthew T. Bell, Jr.,

Rear Admiral, U.S. Coast Guard, Commander, Seventeenth Coast Guard District.

[FR Doc. 2020–05652 Filed 3–17–20; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2020–0093]

Port Access Route Study: Seacoast of North Carolina Including Offshore Approaches to the Cape Fear River and Beaufort Inlet, North Carolina

AGENCY: Coast Guard, DHS.

ACTION: Notice of study; request for comments.

SUMMARY: The Coast Guard is conducting a Port Access Route Study (PARS) to determine whether existing or additional vessel routing measures are necessary along the seacoast of North Carolina and in the approaches to the Cape Fear River and Beaufort Inlet (hereinafter, ''NCPARS''). The study is focused on routes between port approaches and international entry and departure transit areas affecting North Carolina ports. The NCPARS will consider whether existing or additional routing measures are necessary to improve navigation safety due to factors such as planned or potential offshore development, current port capabilities and planned improvements, increased vessel traffic, existing and potential anchorage areas, changing vessel traffic patterns, weather conditions, or navigational difficulty. The aim of vessel routing measures are to reduce the risk of casualties. Examples of potential measures include traffic separation schemes, two-way routes, recommended tracks, deep-water routes, precautionary areas, and areas to be avoided. The recommendations of the study may lead to future rulemakings or appropriate international agreements.

DATES: Comments and related material must be received on or before May 18, 2020. Requests for a public meeting must be submitted on or before April 17, 2020.

ADDRESSES: You may submit comments identified by docket number USCG–2020–0093 using the Federal eRulemaking Portal *http://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTAL INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice or study, call or email Mr. Jerry Barnes, Fifth Coast Guard District (dpw), U.S. Coast Guard; telephone (757) 398–6230, email *Jerry.R.Barnes@uscg.mil;* or Mr. Matt Creelman, Fifth Coast Guard District (dpw), U.S. Coast Guard; telephone (757) 398–6225, email *Matthew.K.Creelman2@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

ACPARS Atlantic Coast Port Access Route Study
AIS Automatic Identification System
COMDTINST Commandant Instruction
DHS Department of Homeland Security
EEZ Exclusive Economic Zone
MTS Marine Transportation System
NCPARS North Carolina Port Access Route Study
PARS Port Access Route Study
TSS Traffic Separation Scheme
USCG United States Coast Guard

II. Public Participation and Request for Comments

We encourage you to participate in this study by submitting comments and related materials. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided.

A. Submitting Comments: If you submit comments to the online public docket, please include the docket number for this a notice (USCG–2020–0093), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. We accept anonymous comments.

To submit your comment online, go to *http://www.regulations.gov,* and insert ''USCG–2020–0093'' in the ''search box.'' Click ''Search'' and then click ''Comment Now.'' We will consider all comments and material received during the comment period.

B. Public Meetings: The Coast Guard may hold public meeting(s) if there is sufficient public interest. You must submit a request for one on or before April 17, 2020. You may submit your request for a public meeting online via *http://www.regulations.gov.* Please explain why you believe a public meeting would be beneficial. If we determine that a public meeting would aid in the study, we will hold a meeting at a time and place announced by a later notice in the **Federal Register**.

C. Viewing Comments and Documents: To view the comments and documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* click on the ''read comments'' box, which will then become highlighted in blue. In the ''Keyword'' box insert ''USCG–2020–0093'' and click ''Search.'' Click the ''Open Docket Folder'' in the ''Actions'' column.

D. Privacy Act: We accept anonymous comments. All comments received will be posted without change to *https://www.regulations.gov* and will include any personal information you have provided. For more about privacy and submissions in response to this document, see DHS's Correspondence System of Records notice (84 FR 48645, September 26, 2018). Documents mentioned in this notice as being available in the docket, and all public comments, will be in our online docket at *https://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

III. Background and Purpose

A. Requirements for Port Access Route Studies: Under Section 70003 of Title 46 of the United States Code, the Commandant of the Coast Guard may designate necessary fairways and traffic separation schemes (TSSs) to provide safe access routes for vessels proceeding to and from U.S. ports. The designation of fairways and TSSs recognizes the paramount right of navigation over all other uses in the designated areas.

Before establishing or adjusting fairways or TSSs, the Coast Guard must conduct a PARS, *i.e.,* a study of potential traffic density and the need for safe access routes for vessels. Through the study process, the Coast Guard must coordinate with federal, state, and foreign state agencies (as appropriate) and consider the views of maritime community representatives, environmental groups, and other interested stakeholders. The primary purpose of this coordination is, to the extent practicable, to reconcile the need for safe access routes with other reasonable waterway uses such as construction and operation of renewable energy facilities and other uses.

In addition to aiding the Coast Guard in establishing new or adjusting fairways or TSSs, the NCPARS may recommend establishing or amending other vessel routing measures. Examples of other routing measures, among others, include two-way routes, recommended tracks, deep-water routes (for the benefit primarily of ships whose ability to maneuver is constrained by their draft), precautionary areas (where ships must navigate with particular caution), and areas to be avoided (for reasons of exceptional danger or especially sensitive ecological and environmental factors).

B. Previous Port Access Route Studies: The Coast Guard last studied the approaches to the Cape Fear River and Beaufort Inlet in 2002, and published the final results in 2004 (69 FR 18476, April 8, 2004). The study was conducted in response to an increase in vessel size, traffic density and channel depth and width since the initial 1981 PARS. Study available at *https://www.navcen.uscg.gov/pdf/PARS/CAPE_FEAR_RIVER_PARS.pdf.*

In 2016, the Coast Guard published a notice of its Atlantic Coast Port Access Route Study (ACPARS) (81 FR 13307, March 14, 2016) that analyzed the Atlantic Coast waters seaward of existing port approaches within the U.S. Exclusive Economic Zone (EEZ) and announced the report as final in 2017 (82 FR 16510, April 5, 2017). This multiyear study began in 2011, included public participation, and identified the navigation routes customarily followed by ships engaged in commerce between international and domestic U.S. ports. Study available at *https://navcen.uscg.gov/?pageName=PARSReports.* The ACPARS analyzed waters located seaward of existing port approaches within the EEZ along the entire Atlantic Coast. Automatic Identification System (AIS) data and information from stakeholders were used to identify and verify deep draft and coastwise navigation routes that are typically followed by ships engaged in commerce between international and domestic U.S. ports. Additional analysis of sea space for vessels to maneuver in compliance with the International Regulations for Preventing Collisions at Sea led to development of marine planning guidelines and recommendations for shipping safety fairways.

C. Need for a New Port Access Route Study: In 2019, the Coast Guard announced a new study of routes used by ships to access ports on the Atlantic Coast of the United States (84 FR 9541, March 15, 2019). This new study of routes supplements and builds on the ACPARS. As part of the study, the Coast Guard will conduct several PARS, including the NCPARS, to examine ports along the Atlantic coast that are economically significant, support military operations or critical national defense and related international entry and departure transit areas that are integral to the safe and efficient and unimpeded flow of commerce to/from major international shipping lanes.

Vessel size, traffic density, and cargo volume have increased significantly since the 2002 study. Major channel depth, width and alignment changes are anticipated to occur in the Cape Fear River and Port of Wilmington, NC. Potential federal navigation project improvements under consideration by the U.S. Army Corps of Engineers include deepening the existing federal navigation channel to the Port of Wilmington, extending the ocean entrance channel farther offshore, and widening channels in the Cape Fear River where needed.[1]

The purpose of this notice is to announce commencement of the NCPARS to examine the seacoast of North Carolina and the offshore approaches to the Cape Fear River and Beaufort Inlet, in conjunction with the implementation of recommendations of the ACPARS, and to solicit public comments. Similar to the ACPARS, the NCPARS will use automatic identification system (AIS) data and information from stakeholders to identify and verify customary navigation routes as well as potential conflicts involving alternative activities, such as wind energy generation and offshore mineral exploitation and exploration. We encourage you to participate in the study process by submitting comments in response to this notice. Comments should address impacts to navigation along the seacoast of North Carolina and the approaches to the Cape Fear River and Beaufort Inlet resulting from factors such as: Planned or potential offshore development including turbine placements and transmission corridors, current port capabilities and planned improvements, increased vessel traffic, changing vessel traffic patterns, weather conditions, potential conflicts or disruptions in uncharted or informal anchorage areas, or navigational difficulty.

[1] 84 FR 48132, Sept. 12, 2019 (U.S. Army Corps of Engineers ''Notice of Intent to Prepare a Draft Environmental Impact Statement (DEIS) for the Wilmington Harbor Navigation Improvement Project Integrated Feasibility Study and Environmental Report, New Hanover and Brunswick Counties, NC'').

IV. Cape Fear and Beaufort Inlet, NC PARS: Timeline, Study Area, and Process

The Fifth Coast Guard District and Coast Guard Sector North Carolina will conduct this PARS. The study will commence upon publication of this notice and may take 12 months or more to complete.

The study area is described as an area bounded by a line connecting the following geographic positions:

- 75°30′ W, 35°19′ N;
- 71°16′ W, 35°19′ N;
- 74° W, 32° N;
- 78°40′ W, 32°52′ N;
- 79°11′ W, 33°12′ N;

thence along the coast line back to the origin.

This area extends approximately 200 nautical miles seaward of Cape Fear including the offshore area of North Carolina and South Carolina used by commercial and public vessels transiting to and from these ports. An illustration showing the study area is available in the docket where indicated under **ADDRESSES**. Additionally, the study area is available for viewing on the Mid-Atlantic Ocean Data Portal at *http://portal.midatlanticocean.org/visualize/.* See the ''Maritime'' portion of the Data Layers section.

The NCPARS will analyze navigation routes to/from the seacoast of North Carolina and the approaches to the Cape Fear River and Beaufort Inlet, to the proposed fairways outlined in the ACPARS including international routes to/from the United States. Current capabilities and planned improvements to handle maritime conveyances will be considered. Analyses will be conducted in accordance with COMDTINST 16003.2B, Marine Planning to Operate and Maintain the Marine Transportation System (MTS) and Implement National Policy. Instruction available at *https://media.defense.gov/2019/Jul/10/2002155400/-1/-1/0/CI_16003_2B.PDF.*

We will publish the results of the NCPARS in the **Federal Register**. It is possible that the study may validate the status quo (no additional fairways or routing measures) and conclude that no changes are necessary. It is also possible that the study may recommend one or more changes to address navigational safety and the efficiency of vessel traffic management. The recommendations may lead to future rulemakings or appropriate international agreements.

This notice is published under the authority of 5 U.S.C. 552(a).

Keith M. Smith,

Rear Admiral, U.S. Coast Guard, Commander, Fifth Coast Guard District.

[FR Doc. 2020–05653 Filed 3–17–20; 8:45 am]

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–6198–N–01]

Announcement of Tenant Protection Voucher Funding Awards for Fiscal Year 2019 for the Housing Choice Voucher Program

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Announcement of Fiscal Year 2019 awards.

SUMMARY: In accordance with Section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989, this document notifies the public of Tenant Protection Voucher (TPV) funding awards for Fiscal Year (FY) 2019 to public housing agencies (PHAs) under the Section 8 Housing Choice Voucher Program (HCVP). The purpose of this notice is to publish the names and addresses of awardees, and the amount of their non-competitive funding awards for assisting households affected by housing conversion actions, public housing relocations and replacements, moderate rehabilitation replacements, and Choice Neighborhoods and HOPE VI voucher awards.

FOR FURTHER INFORMATION CONTACT: Danielle L. Bastarache, Deputy Assistant Secretary, Office of Public Housing and Voucher Programs, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 Seventh Street SW, Room 4204, Washington, DC 20410–5000, telephone (202) 402–1380 (this is not a toll-free number). Persons with hearing or speech impairments may access this number via TTY by calling the Federal Relay Service at 800–877–8389 (toll-free number).

SUPPLEMENTARY INFORMATION: The regulations governing the HCVP are published at 24 CFR 982. The purpose of the rental assistance program is to assist eligible families to pay their rent for decent, safe, and sanitary housing in the private rental market. The regulations for allocating housing assistance budget authority under Section 213(d) of the Housing and Community Development Act of 1974 are published at 24 CFR part 791, subpart D.

The FY 2019 awardees announced in this notice were provided HCVP tenant protection vouchers (TPVs) funds on an as-needed, non-competitive basis, *i.e.,* not under the provisions of a Notice of Funding Availability (NOFAs). TPV awards made to PHAs for program actions that displace families living in public housing were made on a first-come, first-served basis in accordance with PIH Notice 2018–04, Voucher Funding in Connection with the Demolition or Disposition of Occupied Public Housing Units, and PIH Notice 2018–09, ''Implementation of the Federal Fiscal Year (FFY) 2019 Funding Provision for the Housing Choice Voucher Program.'' Awards for the Rental Assistance Demonstration (RAD) were provided for Rental Supplement and Rental Assistance Payment Projects (RAD Second Component) consistent with PIH Notice H–2019–09 PIH–2019–23(HA), REV–4, ''Rental Assistance Demonstration-Final Implementation, Revision 4.'' Announcements of awards provided under the NOFA process for Mainstream, Designated Housing, Family Unification (FUP), and Veterans Assistance Supportive Housing (VASH) programs are published in a separate **Federal Register** notice.

Awards published under this notice were provided to assist families: (1) Living in federal public housing units previously owned by PHAs and subsequently demolished, converted to Section 8 assistance, sold, or otherwise disposed; (2) affected by the expiration or termination of their Project-based Section 8 and Moderate Rehabilitation contracts; (3) in properties where the owner has prepaid the HUD mortgage; (4) in projects where the Rental Supplement and Rental Assistance Payments contracts are expiring (RAD—Second Component); (5) relocated in connection with the demolition of public housing; (6) provided replacement housing assistance for single room occupancy (SRO) units that fail housing quality standards (HQS); (7) in public housing developments scheduled for demolition in connection with a HUD-approved Choice Neighborhoods or HOPE VI revitalization and (8) consistent with PIH Notice 2019–01, ''Funding Availability for Tenant Protection Voucher for Certain At-Risk Households in Low Vacancy Areas-Fiscal Year 2019.''

A special administrative fee of $200 per occupied unit was provided to PHAs to compensate for any extraordinary HCVP administrative costs associated with the Multifamily Housing conversion actions.

The Department awarded total new budget authority of $118,418,829 to recipients under all the above-mentioned categories for 12,111 housing choice vouchers. This budget authority includes $620,877 of unobligated commitments made in FY 2018. These funds were reserved by September 30, 2018, but not contracted until FY 2019, and thus have been included with obligated commitments for FY 2019.

In accordance with Section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989 (103 Stat. 1987, 42 U.S.C. 3545), the Department is publishing the names and addresses of awardees, and their award amounts in Appendix A. The awardees are listed alphabetically by State for each type of TPV award.

Dated: March 2, 2020.

R. Hunter Kurtz,

Assistant Secretary for Public and Indian Housing.

BILLING CODE 4210–67–P

Section 8 Rental Assistance Programs Announcement of Awards for Fiscal Year 2019				
Housing Agency	Address	Units	HAP Award	Fee Award
Public Housing Tenant Protection Actions				
Housing Agency	Address	Units	Award	
	Choice Neighborhood Relocation		HAP	Not applicable
MD: HOUSING AUTHORITY OF BALTIMORE	417 EAST FAYETTE STREET, BALTIMORE, MD 21201	120	$1,198,392	
MI: FLINT HOUSING COMMISSION	3820 RICHFIELD ROAD, FLINT, MI 48506	82	$459,351	
MO: ST. LOUIS HOUSING AUTHORITY	3520 PAGE BOULEVARD, ST. LOUIS, MO 63106	64	$453,758	
	Total for Choice Neighborhood Relocation	**266**	**$2,111,501**	
	Choice Neighborhood Replacement			
KY: LOUISVILLE HOUSING AUTHORITY	420 SOUTH EIGHTH STREET, LOUISVILLE, KY 40203	241	$1,914,822	
MA: BOSTON HOUSING AUTHORITY	52 CHAUNCY STREET, BOSTON, MA 02111	33	$476,487	
OK: TULSA HOUSING AUTHORITY	P O BOX 6369, TULSA, OK 74148	77	$457,398	
	Total for Choice Neighborhood Replacement	**351**	**$2,848,707**	
	Mod Replacements			
AZ: CITY OF TUCSON HA	310 N COMMERCE PARK LOOP, TUCSON, AZ 85745	21	$134,316	
CO: HOUSING AUTH OF CITY OF GREELEY	P. O. BOX 130, GREELEY, CO 80632	167	$1,184,564	
FL: MIAMI DADE HOUSING AUTHORITY	701 NW 1ST COURT, 16TH FLOOR, MIAMI, FL 33136	26	$284,917	
MD: HOUSING AUTHORITY OF BALTIMORE	417 EAST FAYETTE STREET, BALTIMORE, MD 21201	0	$21,686	
ME: LEWISTON HOUSING AUTHORITY	JDOWLING@LEWIS 1 COLLEGE STREET, LEWISTON, ME 04240	6	$35,776	
MN: MINNEAPOLIS PHA	1001 WASHINGTON AVE NORTH, MINNEAPOLIS, MN 55401	15	$145,175	
NY: HA OF BEACON	1 FORRESTAL HEIGHTS, BEACON, NY 12508	8	$77,966	
NY: TOWN OF AMHERST	C/O BELMONT HOUSING RESOURCES 1195 MAIN STREET, BUFFALO, NY	2	$10,896	
OH: STARK METROPOLITAN HOUSING AUTH.	400 EAST TUSCARAWAS STREET, CANTON, OH 44702	6	$33,208	
OH: PORTAGE MHA	2832 STATE ROUTE 59, RAVENNA, OH 44266	42	$268,185	
OK: TULSA HOUSING AUTHORITY	P O BOX 6369, TULSA, OK 74148	12	$72,831	
SC: CITY OF SPARTANBURG H/A	P O BOX 2828, SPARTANBURG, SC 29304	36	$194,681	
TN: HSG DEV AGENCY ELIZABETHTON	P. O. BOX 637, ELIZABETHTON, TN 37644	8	$34,004	
TX: HARRIS COUNTY HSG AUTHORITY	8933 INTERCHANGE, HOUSTON, TX 77054	2	$25,776	
UT: HA OF CITY OF OGDEN	1100 GRANT AVE., OGDEN, UT 84404	13	$68,615	
WA: PIERCE COUNTY HOUSING AUTHORITY	603 S POLK STREET PO BOX 45410, TACOMA, WA 98445	16	$148,370	
WV: HOUSING AUTHORITY CITY OF BLUEFIELD	P O BOX 1475 1600 HILL AVENUE, BLUEFIELD, WV 24701	5	$21,584	
	Total for Mod Replacements	**385**	**$2,762,550**	
	MTW Relocation/Replacement			
DC: D.C HOUSING AUTHORITY	1133 NORTH CAPITOL STREET NE, WASHINGTON, DC 20002	164	$2,533,169	
MA: CAMBRIDGE HOUSING AUTHORITY	675 MASSACHUSETTS AVENUE, CAMBRIDGE, MA 02139	124	$2,145,265	
MA: HOLYOKE HOUSING AUTHORITY	475 MAPLE STREET, HOLYOKE, MA 01040	76	$498,290	
MD: HOUSING AUTHORITY OF BALTIMORE	417 EAST FAYETTE STREET, BALTIMORE, MD 21201	125	$1,274,910	
OR: HOME FORWARD (PORTLAND HOUSING	135 SW ASH STREET, PORTLAND, OR 97204	190	$1,648,736	
TX: SAN ANTONIO HOUSING AUTHORITY	818 S. FLORES STREET PO BOX 1300, SAN ANTONIO, TX 78295	94	$650,427	
	Total for MTW Relocation/Replacement	**773**	**$8,750,797**	
	Relocation-Sunset			
FL: CITY OF LAKELAND H/A	P O BOX 1009 430 S. HARTSELL AVENUE, LAKELAND, FL 33815	14	$108,614	
RQ: PUERTO RICO DEPT OF HOUSING	PO BOX 21365, SAN JUAN, PR 00928	86	$509,808	
	Total for Relocation-Sunset	**100**	**$618,422**	

	Replacement			
AL: HSG AUTH OF BIRMINGHAM DISTRICT	1826 3RD AVE. SOUTH, BIRMINGHAM, AL 35233	273	$1,974,904	
AL: HA HUNTSVILLE	P O BOX 486, HUNTSVILLE, AL 35804	166	$1,040,322	
AL: HA TROY	P O DRAWER 289, TROY, AL 36081	74	$315,560	
AR: HOUSING AUTHORITY OF THE CITY OF	P O BOX 8872, PINE BLUFF, AR 71611	20	$99,360	
CA: SAN FRANCISCO HSG AUTH	1815 EGBERT AVE., SAN FRANCISCO, CA 94124	76	$2,163,205	
CA: HOUSING AUTHORITY COUNTY OF KERN	601 24TH STREET, BAKERSFIELD, CA 93301	26	$167,444	
CA: CITY OF SAN LUIS OBISPO HOUSING	P.O. BOX 1289 487 LEFF STREET, SAN LUIS OBISPO, CA 93406	41	$386,426	
CO: HOUSING AUTHORITY OF THE CITY AND	777 GRANT STREET, DENVER, CO 80203	3	$37,124	
CT: BRIDGEPORT HOUSING AUTHORITY	150 HIGHLAND AVENUE, BRIDGEPORT, CT 06604	116	$1,268,487	
FL: HOUSING AUTHORITY OF JACKSONVILLE	1300 BROAD STREET, JACKSONVILLE, FL 32202	22	$159,591	
FL: SARASOTA HOUSING AUTHORITY	269 S OSPREY AVE SUITE 100, SARASOTA, FL 34236	60	$573,933	
FL: CITY OF LAKELAND H/A	P O BOX 1009 430 S. HARTSELL AVENUE, LAKELAND, FL 33815	49	$380,147	
FL: PANAMA CITY HSG AUTH	804 E 15TH STREET, PANAMA CITY, FL 32405	218	$1,620,690	
ID: IDAHO HOUSING AND FINANCE	565 W MYRTLE STREET PO BOX 7899, BOISE, ID 83707	8	$39,448	
IL: CITY OF DANVILLE HOUSING AUTHORITY	1607 CLYMAN LANE, DANVILLE, IL 61832	57	$281,152	
IL: ROCKFORD HOUSING AUTHORITY	223 SOUTH WINNEBAGO STREET, ROCKFORD, IL 61102	348	$2,167,468	
IL: HSG AUTH OF THE COUNTY OF SHELBY	P O BOX 252, SHELBYVILLE, IL 62565	82	$226,447	
KY: LEXINGTON FAYETTE URBAN COUNTY	300 NEW CIRCLE ROAD, LEXINGTON, KY 40505	183	$1,364,990	
MA: BOSTON HOUSING AUTHORITY	52 CHAUNCY STREET, BOSTON, MA 02111	235	$3,414,174	
MA: CAMBRIDGE HOUSING AUTHORITY	675 MASSACHUSETTS AVENUE, CAMBRIDGE, MA 02139	7	$129,475	
MA: BROOKLINE HOUSING AUTHORITY	90 LONGWOOD AVE, BROOKLINE, MA 02146	25	$443,094	
MN: RENVILLE COUNTY HRA	500 EAST DEPUE AVENUE, OLIVIA, MN 56277	2	$8,032	
MN: CLAY COUNTY HRA	P.O. BOX 99, DILWORTH, MN 56529	24	$136,561	
MS: HA TENNESSEE VALLEY	P O BOX 1329, CORINTH, MS 38834	20	$90,122	
MS: MISS REGIONAL H/A VIII	P O BOX 2347, GULFPORT, MS 39505	100	$690,757	
NC: HA HIGH POINT	500 E RUSSELL AVENUE PO BOX 1779, HIGH POINT, NC 27261	102	$615,439	
NC: TWIN RIVERS OPPORTUNITIES INC	318 CRAVEN STREET PO BOX 1482, NEW BERN, NC 28563	108	$625,968	
ND: HOUSING AUTHORITY OF CASS COUNTY	230 8TH AVE WEST, WEST FARGO, ND 58078	60	$328,248	
NM: ALBUQUERQUE HSG AUTHORITY	1840 UNIVERSITY BLVD. SE, ALBUQUERQUE, NM 87106	8	$52,464	
NY: NEW YORK CITY HOUSING AUTHORITY	90 CHURCH STREET, 9TH FLOOR LEASED HOUSING, NEW YORK, NY 10007	1,192	$15,153,491	
NY: HA OF FREEPORT	3 BUFFALO AVENUE, FREEPORT, NY 11520	99	$1,749,710	
NY: HA OF SCHENECTADY	375 BROADWAY, SCHENECTADY, NY 12305	71	$463,632	
OH: CINCINNATI METROPOLITAN HSG AUTH.	1635 WESTERN AVE, CINCINNATI, OH 45214	20	$130,937	
OK: OKLAHOMA CITY HOUSING AUTHORITY	1700 N E FOURTH STREET, OKLAHOMA CITY, OK 73117	37	$439,116	
RQ: PUERTO RICO DEPT OF HOUSING	PO BOX 21365, SAN JUAN, PR 00928	63	$373,464	
SC: HA COLUMBIA	1917 HARDEN STREET, COLUMBIA, SC 29204	239	$1,655,466	
TN: CHATTANOOGA H/A	P O BOX 1486, CHATTANOOGA, TN 37402	48	$305,947	
TX: HOUSING AUTHORITY OF EL PASO	5300 PAISANO, EL PASO, TX 79905	45	$265,334	
TX: FORT WORTH HOUSING SOLUTIONS	P.O. BOX 430, 1201 E. 13TH ST., FORT WORTH, TX 76101	298	$2,300,262	
TX: HOUSING AUTHORITY OF LUBBOCK	P.O. BOX 2568 1708 AVENUE G, LUBBOCK, TX 79408	72	$470,612	
TX: HSG AUTH CITY OF BRENHAM	P O BOX 623 1901 NORTHVIEW CIRCLE DRIVE, BRENHAM, TX 77833	19	$87,552	
TX: BEXAR COUNTY HSG AUTHORITY	1017 N. MAIN AVE., SUITE 201, SAN ANTONIO, TX 78212	30	$219,469	
UT: HA OF THE COUNTY OF SALT LAKE	3595 S. MAIN STREET, SALT LAKE CITY, UT 84115	127	$1,040,648	
VA: PORTSMOUTH REDEVELOPMENT & H/A	PO BOX 1098 3116 SOUTH STREET, PORTSMOUTH, VA 23705	74	$597,953	
VA: RICHMOND REDEVELOPMENT & H/A	901 CHAMBERLAYNE PARKWAY P.O. BOX 26887, RICHMOND, VA 23261	7	$57,317	
WA: HOUSING AUTHORITY CITY OF EVERETT	3107 COLBY AVE PO BOX 1547, EVERETT, WA 98206	78	$918,936	
WA: HA OF THE CITY OF RENTON	2900 NE 10TH STREET, RENTON, WA 98056	34	$434,744	
WA: BELLINGHAM HOUSING AUTHORITY	208 UNITY ST LOWER LEVEL PO BOX 9701, BELLINGHAM, WA 98225	23	$166,108	
WI: SHEBOYGAN HA	PO BOX 1052, SHEBOYGAN, WI 53082	105	$586,064	
	Total for Replacement	**5,194**	**$48,217,794**	

	SRO-Relocation/Replacement CPD			
CO: HA OF THE CITY AND COUNTY OF DENVER	777 GRANT STREET, DENVER, CO 80203	46	$595,536	
MD: HOUSING AUTHORITY OF BALTIMORE	417 EAST FAYETTE STREET, BALTIMORE, MD 21201	76	$791,981	
NJ: NEW JERSEY DEPARTMENT OF	101 SOUTH BROAD STREET POST OFFICE BOX 051, TRENTON, NJ 08625	7	$72,809	
TX: HOUSING AUTHORITY OF EL PASO	5300 PAISANO, EL PASO, TX 79905	39	$230,476	
	Total for SRO-Relocation/Replacement CPD	**168**	**$1,690,802**	
	Witness Relocation Assistance			
MD: MONTGOMERY CO HOUSING AUTHORITY	10400 DETRICK AVENUE, KENSINGTON, MD 20895	5	$106,593	
	Total for Witness Relocation Assistance	**5**	**$106,593**	
	Total for Public Housing TP	**7,242**	**$ 67,107,166**	
Multifamily Housing Conversion Actions				
	Certain At-Risk Households Low Vacancy		**HAP**	**Special Fees**
CA: CITY OF SANTA MONICA	1901 MAIN ST. STE. A, SANTA MONICA, CA 90405	306	$4,314,894	$61,200
FL: HOUSING AUTHORITY OF JACKSONVILLE	1300 BROAD STREET, JACKSONVILLE, FL 32202	42	$304,673	$8,400
FL: PINELLAS COUNTY H/A	11479 ULMERTON ROAD, LARGO, FL 33778	110	$876,018	$22,000
MA: WORCESTER HOUSING AUTHORITY	40 BELMONT STREET, WORCESTER, MA 01605	34	$260,214	$6,800
MD: MONTGOMERY CO HOUSING AUTHORITY	10400 DETRICK AVENUE, KENSINGTON, MD 20895	264	$3,597,454	$52,800
MI: MICHIGAN STATE HSG. DEV. AUTH.	P.O. BOX 30044, LANSING, MI 48909	34	$223,115	$6,800
MN: METROPOLITAN COUNCIL HRA	390 ROBERT STREET NORTH, ST. PAUL, MN 55101	40	$368,002	$8,000
NY: NYS HSG TRUST FUND CORPORATION	38-40 STATE STREET, ALBANY, NY 12207	16	$170,412	$3,200
PA: ALLENTOWN HOUSING AUTHORITY	1339 ALLEN STREET, ALLENTOWN, PA 18102	83	$629,721	$16,600
	Total for Certain At-Risk Households Low Vacancy	**929**	**$10,744,503**	**$185,800**
	Mod Rehab SRO - RAD			
CA: SAN FRANCISCO HSG AUTH	1815 EGBERT AVE., SAN FRANCISCO, CA 94124	140	$2,947,997	$28,000
CA: CITY OF LOS ANGELES HSG AUTH	2600 WILSHIRE BLVD., 3RD FLOOR, LOS ANGELES, CA 90057	53	$600,130	$10,600
CO: HA OF THE CITY AND COUNTY OF DENVER	777 GRANT STREET, DENVER, CO 80203	88	$1,088,958	$17,600
MA: AMESBURY HSG AUTHORITY	180 MAIN ST, AMESBURY TOWN, MA 01913	24	$244,005	$4,800
NY: THE CITY OF NEW YORK	DEPT OF HSG PRESERVATION & DEV 100 GOLD STREET ROOM 501, NY	14	$174,475	$2,800
OR: HOME FORWARD-PORTLAND HOUSING	135 SW ASH STREET, PORTLAND, OR 97204	361	$3,317,229	$72,200
WA: SEATTLE HOUSING AUTHORITY	120 SIXTH AVENUE NORTH PO BOX 19028, SEATTLE, WA 98109	245	$3,046,719	$49,000
WA: HOUSING AUTHORITY OF THURSTON	1206 12TH AVENUE SE, OLYMPIA, WA 98501	43	$312,366	$8,600
	Total for Mod Rehab SRO - RAD	**968**	**$11,731,879**	**$193,600**
	PD Relocation Vouchers			
AL: HA GREATER GADSDEN	P O BOX 1219, GADSDEN, AL 35902	76	$324,252	$15,200
MI: MICHIGAN STATE HSG. DEV. AUTH.	P.O. BOX 30044, LANSING, MI 48909	170	$1,076,692	$34,000
	Total for PD Relocation Vouchers	**246**	**$1,400,944**	**$49,200**
	Pre-payment Vouchers			
CT: HSG AUTH OF CITY OF NEW HAVEN	360 ORANGE STREET, NEW HAVEN, CT 06511	70	$1,042,549	$14,000
FL: MIAMI DADE HOUSING AUTHORITY	701 NW 1ST COURT, 16TH FLOOR, MIAMI, FL 33136	267	$3,057,962	$53,400
MA: CAMBRIDGE HOUSING AUTHORITY	675 MASSACHUSETTS AVENUE, CAMBRIDGE, MA 02139	136	$2,867,375	$27,200
MA: QUINCY HOUSING AUTHORITY	80 CLAY STREET, QUINCY, MA 02170	120	$1,670,054	$24,000
MA: SPRINGFIELD HSG AUTHORITY	60 CONGRESS P O BOX 1609, SPRINGFIELD, MA 01101	241	$2,032,353	$48,200
MA: FALMOUTH HSG AUTHORITY	115 SCRANTON AVE, FALMOUTH TOWN, MA 02540	71	$763,954	$14,200
MA: OXFORD H A	23 WHEELOCK ST, OXFORD, MA 01540	62	$475,275	$12,400
NJ: JERSEY CITY HOUSING AUTHORITY	400 US HIGHWAY #1, JERSEY CITY, NJ 07306	14	$147,188	$2,800
NY: THE CITY OF NEW YORK	DEPT OF HSG PRESERVATION & DEV 100 GOLD STREET ROOM 501, NEW	83	$1,051,318	$16,600
	Total for Pre-payment Vouchers	**1,064**	**$13,108,028**	**$212,800**
	Relocation 8bb-sunset			
FL: CITY OF MIAMI, DEPT. OF COMMUNITY	444 S.W. 2ND AVENUE, 2ND FLOOR, MIAMI, FL 33130	2	$26,776	$400
MA: WORCESTER HOUSING AUTHORITY	40 BELMONT STREET, WORCESTER, MA 01605	1	$7,661	$200
TX: HARRIS COUNTY HSG AUTHORITY	8933 INTERCHANGE, HOUSTON, TX 77054	232	$2,036,886	$46,400
	Total for Relocation 8bb-sunset	**235**	**$2,071,323**	**$47,000**

	Termination/Opt-out Vouchers			
CA: CITY OF LOS ANGELES HSG AUTH	2600 WILSHIRE BLVD., 3RD FLOOR, LOS ANGELES, CA 90057	5	$56,616	$2,200
CA: COUNTY OF SACRAMENTO HOUSING	801 12TH STREET, SACRAMENTO, CA 95814	48	$412,543	$9,600
CA: COUNTY OF SOLANO HSG AUTH	SUITE 5500 675 TEXAS ST., FAIRFIELD, CA 94533	19	$158,143	$3,800
CT: HARTFORD HOUSING AUTHORITY	160 OVERLOOK TERRACE, HARTFORD, CT 06106	52	$465,585	$10,400
CT: CITY OF HARTFORD	250 CONSTITUTION PLAZA, HARTFORD, CT 06103	70	$620,701	$14,000
DC: D.C HOUSING AUTHORITY	1133 NORTH CAPITOL STREET NE, WASHINGTON, DC 20002	10	$149,948	$2,000
FL: HOUSING AUTHORITY OF JACKSONVILLE	1300 BROAD STREET, JACKSONVILLE, FL 32202	205	$1,476,713	$41,000
FL: MIAMI DADE HOUSING AUTHORITY	701 NW 1ST COURT, 16TH FLOOR, MIAMI, FL 33136	27	$291,869	$5,400
FL: HA OF THE CITY OF FORT MYERS	4224 RENAISSANCE PRESERVE WAY, FORT MYERS, FL 33916	38	$265,182	$7,600
GA: HA AUGUSTA	P O BOX 3246 1435 WALTON WAY, AUGUSTA, GA 30914	85	$589,846	$17,000
GA: GEORGIA DEPT. OF COMMUNITY AFFAIRS-	60 EXECUTIVE PARK SOUTH, NE SUITE 250, ATLANTA, GA 30329	30	$223,528	$6,000
IA: NORTHWEST IOWA REGIONAL HA	P O BOX 446 919 2ND AVENUE, SW, SPENCER, IA 51301	20	$71,016	$4,000
IL: HOUSING AUTHORITY OF COOK COUNTY	175 WEST JACKSON BOULEVARD SUITE 350, CHICAGO, IL 60604	46	$439,420	$9,200
IL: DUPAGE COUNTY HOUSING AUTHORITY	711 EAST ROOSEVELT ROAD, WHEATON, IL 60187	2	$39,128	$800
IN: NOBLESVILLE HOUSING AUTHORITY	320 KINGS LANE, NOBLESVILLE, IN 46060	4	$26,149	$800
LA: EAST BATON ROUGE PH. HSG. AUTHORITY	4731 NORTH BLVD., BATON ROUGE, LA 70806	10	$80,003	$2,000
MA: SOMERVILLE HOUSING AUTHORITY	30 MEMORIAL ROAD, SOMERVILLE, MA 02145	4	$64,392	$800
MD: MONTGOMERY CO HOUSING AUTHORITY	10400 DETRICK AVENUE, KENSINGTON, MD 20895	58	$779,554	$11,600
MD: ANNE ARUNDEL COUNTY HOUSING AUTH.	7885 GORDON COURT P.O. BOX 817, GLEN BURNIE, MD 21060	8	$92,376	$1,600
MI: DETROIT HOUSING COMMISSION	1301 EAST JEFFERSON AVENUE, DETROIT, MI 48207	15	$112,055	$3,000
MI: PLYMOUTH HOUSING COMMISSION	1160 SHERIDAN, PLYMOUTH, MI 48170	48	$311,524	$9,600
MI: WESTLAND HOUSING COMMISSION	32715 DORSEY ROAD, WESTLAND, MI 48186	8	$48,281	$1,600
MI: MICHIGAN STATE HSG. DEV. AUTH.	P.O. BOX 30044, LANSING, MI 48909	18	$154,617	$3,600
MN: WORTHINGTON HRA	819 TENTH STREET, WORTHINGTON, MN 56187	22	$107,522	$4,400
MN: ST LOUIS PARK HRA	5005 MINNETONKA BLVD., ST. LOUIS PARK, MN 55416	32	$267,233	$6,400
MN: NW MN MULTI-COUNTY HRA	PO BOX 128, MENTOR, MN 56736	8	$41,498	$1,600
MN: KANDIYOHI COUNTY HRA	2200 23RD STREET, N.E., # 2090, WILLMAR, MN 56201	42	$223,559	$8,400
MO: ST. LOUIS HOUSING AUTHORITY	3520 PAGE BOULEVARD, ST. LOUIS, MO 63106	53	$375,768	$10,600
MO: HOUSING AUTHORITY OF KANSAS CITY	920 MAIN STREET SUITE 701, KANSAS CITY, MO 64106	12	$85,888	$1,800
NC: COLUMBUS CTY PHA	715 N LEGION ROAD PO BOX 829, WHITEVILLE, NC 28472	18	$117,133	$5,600
ND: HOUSING AUTHORITY OF THE COUNTY OF	PO BOX 5, ASHLEY, ND 58413	13	$45,708	$2,600
NE: SCOTTS BLUFF COUNTY HOUSING	89-A WOODLEY PARK ROAD, GERING, NE 69341	8	$34,191	$1,600
NH: MANCHESTER HOUSING AUTHORITY	198 HANOVER STREET, MANCHESTER, NH 03104	48	$439,379	$9,600
NJ: NEW BRUNSWICK HA	7 VAN DYKE AVENUE, NEW BRUNSWICK, NJ 08901	21	$257,620	$4,200
OH: CINCINNATI METROPOLITAN HSG.AUTH.	1635 WESTERN AVE, CINCINNATI, OH 45214	11	$71,986	$2,200
OH: TUSCARAWAS MHA	134 2ND STREET SW, NEW PHILADELPHIA, OH 44663	39	$162,508	$7,800
PA: BEAVER COUNTY HOUSING AUTHORITY	300 STATE STREET, BEAVER, PA 15009	6	$30,126	$1,200
SD: MEADE COUNTY HOUSING &	1220 CEDAR STREET #113, STURGIS, SD 57785	6	$27,621	$1,200
SD: BROOKINGS HOUSING & REDEVELOPMENT	1310 MAIN AVE. SOUTH, BROOKINGS, SD 57006	29	$146,863	$5,800
TX: HARRIS COUNTY HSG AUTHORITY	8933 INTERCHANGE, HOUSTON, TX 77054	98	$860,409	$19,600
VT: BURLINGTON HOUSING AUTHORITY	65 MAIN STREET, BURLINGTON, VT 05401	38	$360,154	$7,600
WA: HOUSING AUTH CITY OF KENNEWICK	1915 WEST 4TH PLACE, KENNEWICK, WA 99336	39	$230,743	$7,800
WA: KITSAP COUNTY CONSOLIDATED	9307 BAYSHORE DR NW, SILVERDALE, WA 98383	29	$227,004	$5,800
WA: HOUSING AUTHORITY OF SNOHOMISH	12711 4TH AVE W, EVERETT, WA 98204	6	$70,972	$1,200
WA: HOUSING AUTHORITY OF THE CITY OF	810 N 6TH AVE, YAKIMA, WA 98902	5	$26,494	$1,000
WA: PIERCE COUNTY HOUSING AUTHORITY	603 S POLK STREET PO BOX 45410, TACOMA, WA 98445	14	$138,618	$2,800
	Total for Termination/Opt-out Vouchers	**1,427**	**$11,278,186**	**$288,400**
	Total for Multifamily Housing Conversion Actions	**4,869**	**$ 50,334,863**	**$ 976,800**
	Grand Total TPV HAP and Fees	**12,111**	**$ 117,442,029**	**$ 976,800**

[FR Doc. 2020–05648 Filed 3–17–20; 8:45 am]

BILLING CODE 4210–67–C

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–VRP–WS–NPS0028013; PPWOVPADW0, PPMPRLE1Y.LB0000 (200); OMB Control Number 1024–0022]

Agency Information Collection Activities; Backcountry/Wilderness Use Permit

AGENCY: National Park Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the National Park Service (NPS) are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before May 18, 2020.

ADDRESSES: Send your comments on this information collection request (ICR) by mail to Phadrea Ponds, Acting Information Collection Clearance Officer, National Park Service, 1201 Oakridge Drive Fort Collins, CO 80525; or by email to *phadrea_ponds@nps.gov.* Please reference Office of Management and Budget (OMB) Control Number 1024–0022 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR contact Roger Semler, Chief, Wilderness Stewardship Division, Visitor & Resource Protection Directorate by email at *roger_semler@nps.gov,* or by telephone at 202–513–7220.

SUPPLEMENTARY INFORMATION: In accordance with the PRA and 5 CFR 1320.8(d)(1), all information collections require approval under the PRA. We may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other Federal agencies to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How might the agency 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 response.

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

Abstract: The Backcountry/Wilderness Use Permit is an extension of the NPS statutory authority and responsibility to protect the park areas it administers and to manage the public use thereof (54 U.S.C. 100101, 100751, 3210102). NPS regulations codified in 36 CFR parts 1 through 7, 12 and 13 are designated to implement statutory mandates that provide for resource protection and pubic enjoyment. In 1976, the NPS initiated a backcountry registration system in accordance with the regulations codified in 36 CFR 1.5, 1.6 and 2.10. The objective of the registration system is to provide users access to backcountry and wilderness areas of national parks with continuing opportunities for solitude. These areas provide primitive and unconfined recreation, while enhancing protection of natural and cultural resources and providing a means of disseminating public safety and outdoor ethics messages regarding backcountry/wilderness travel and camping. The objectives of the permit system are to ensure:

(1) That backcountry user requests are evaluated by park managers in accordance with applicable statutes and NPS regulations;

(2) the consistent use of standards and permitting criteria throughout the agency; and

(3) to the extent possible, the use of a single and efficient permitting document.

By designating access, travel routes and camping locations NPS backcountry/wilderness program managers can redistribute backcountry/wilderness users in response to closures and as a means to manage adverse impacts to natural and cultural resources. The system also facilitates redistribution of backcountry/wilderness users due to public safety hazards related to high fire danger, flood, wind, snow or ice hazards, bear activity, or other situations that may temporarily close or restrict access to a portion of the backcountry/wilderness.

The NPS uses the registration system to:

- Ensure backcountry/wilderness users receive up-to-date information on outdoor ethics,
- serve as an information source for first responders or search and rescue personnel in the event of an emergency in backcountry/wilderness areas.
- monitor the spatial distribution and demographics associated with backcountry/wilderness visitor use.
- inform backcountry and wilderness management, stewardship planning, decision making, and operations.

NPS Forms 10–404, ''Backcountry/Wilderness Use Permit Application'' and 10–404A, ''Backcountry/Wilderness Use Permit Hangtag'' are used to provide access into NPS backcountry areas, including areas that require a reservation to enter in accordance with other NPS regulations.

Title of Collection: Backcountry/Wilderness Use Permit, 36 CFR 1.5, 1.6, and 2.10.

OMB Control Number: 1024–0022.

Form Number: NPS Forms 10–404, ''Backcountry/Wilderness Use Permit'' and 10–404A, ''Backcountry/Wilderness Use Permit Hangtag.''

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Anyone using backcountry and wilderness areas within units of the national park system.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion.

Total Estimated Annual Nonhour Burden Cost: None.

	Annual number of respondents	Avg. time per response (minutes)	Total annual burden hours (rounded)
Form 10–404, Backcountry/Wilderness Use Application	179,200	8	23,893
Form 10–404A, Backcountry/Wilderness Use Permit Hangtag	140,000	5	11,666
Total	319,200		35,559

An agency may not conduct or sponsor nor is a person required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Phadrea Ponds,

Acting Information Collection Clearance Officer, National Park Service.

[FR Doc. 2020–05527 Filed 3–17–20; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRSS–NPS0027926; PPWONRADD3; PPMRSNR1Y.NM0000; 199P103601 (200); OMB Control Number 1024–0236]

Agency Information Collection Activities; Research Permit and Reporting System Applications and Reports

AGENCY: National Park Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the National Park Service (NPS) are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before May 18, 2020.

ADDRESSES: Send your written comments on this information collection request (ICR) by mail to Phadrea Ponds, Acting NPS Information Collection Clearance Officer,1201 Oakridge Drive Fort Collins, CO 80525; or by email to *phadrea_ponds@nps.gov.* Please reference Office of Management and Budget (OMB) Control Number 1024–0236 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Bill Commins by email at *bill_commins@nps.gov,* or by telephone at 202–513–7166.

SUPPLEMENTARY INFORMATION: In accordance with the PRA and 5 CFR 1320.8(d)(1), all information collections require approval under the PRA. We may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other Federal agencies to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How might the agency 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 response.

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

Abstract: NPS policy mandates research studies and specimen collection conducted by researchers, other than NPS employees on official duty, require an NPS scientific research and collecting permit. The permitting process adheres to regulations codified in 36 CFR 2.1 which prohibit the disturbing, removing, or possessing of natural, cultural, and archeological resources. Additionally, regulations codified in 36 CFR 2.5 govern the collection of specimens in parks for the purpose of research, baseline inventories, monitoring, impact analysis, group study, or museum display.

As required by these regulations, a permitting system is managed for scientific research and collecting. NPS Forms 10–741a, ''Application for a Scientific Research and Collecting Permit'' and 10–741b, ''Application for a Science Education Permit,'' are used to collect information from persons seeking a permit to conduct natural or social science research and collection activities in individual units of the National Park System. The information we collect includes, but is not limited to:

- Applicant contact information.
- Project title, purpose of study, summary of proposed field methods and activities, and study and field schedules.
- Location where scientific activities are proposed to take place, including method of access.
- Whether or not specimens are proposed to be collected or handled, and if so, scientific descriptions and proposed disposition of specimens.
- If specimens are to be permanently retained, the proposed repositories for those specimens.

Individuals who receive a permit must report annually on the activities conducted under the permit. Form 10–226, ''Investigator's Annual Report'' collects the following information:

- Reporting year, park, and type of permit.
- Applicant contact information, and names of additional investigators.
- Project title, park-assigned study or activity number, park-assigned permit number, permit start and expiration dates, and scientific study start and ending dates.

• Activity type, subject discipline, purpose of study or activity during the reporting year, and finding and status of study or accomplishments of education activity during the reporting year.

We use the information in this collection to manage the use and preservation of park resources, and to report the status of permitted research and collecting activities. We encourage respondents to use the web-based, automated Research Permit and Reporting System (RPRS) to complete and submit applications and reports. Additional information about existing applications, reporting forms, guidance and explanatory material can be found on the RPRS website (*https://irma.nps.gov/RPRS/*).

Title of Collection: Research Permit and Reporting System Applications and Reports, 36 CFR 2.1 and 2.5.

OMB Control Number: 1024–0236.

Form Number: NPS Forms 10–226, 10–741a, and 10–741b.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Individuals/households; businesses; academic and research institutions; and Federal, State, local, and tribal governments.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion for applications; annually for reports.

Total Estimated Annual Nonhour Burden Cost: None.

	Annual respondents	Total annual responses	Avg. time per response (minutes)	Total annual burden hours (rounded)
Form 10–226, "Investigator's Annual Report":				
Individual	217	217	15	54
Private Sector	1,700	1,700	15	425
State, Local, or Tribal Governments	1,300	1,300	15	325
Total	3,217	3,217	.....	804
Form 10–741a, "Application for a Scientific Research and Collecting Permit":				
Individual	272	272	98	444
Private Sector	1,600	1,600	98	2,613
State, Local, or Tribal Governments	1,400	1,400	98	2,287
Total	3,272	3,272	.....	5,344
Form 10–741b, "Application for a Science Education Permit":				
Individual	30	30	60	30
Private Sector	50	50	60	50
State, Local, or Tribal Governments	50	50	60	50
Total	130	130	.....	130
Totals	6,619	6,619	.....	6,278

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Phadrea Ponds,

Acting Information Collection Clearance Officer, National Park Service.

[FR Doc. 2020–05529 Filed 3–17–20; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–BSAD–CONC–NPS0028674; PPWOBSADC6, PPMVSCS1Y.Y00000, (200) P103601; OMB Control Number 1024–0233]

Agency Information Collection Activities; National Park Service Leasing Program

AGENCY: National Park Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the National Park Service (NPS) are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before May 18, 2020.

ADDRESSES: Send your comments on this information collection request (ICR) by mail to Phadrea Ponds, Acting Information Collection Clearance Officer, National Park Service, 1201 Oakridge Drive Fort Collins, CO 80525; or by email to *phadrea_ponds@nps.gov.* Please reference Office of Management and Budget (OMB) Control Number 1024–0233 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Gordy Kito by email at *gordy_kito@nps.gov,* or by telephone at 202–354–2096.

SUPPLEMENTARY INFORMATION: In accordance with the PRA and 5 CFR 1320.8(d)(1), all information collections require approval under the PRA. We may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other Federal agencies to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How might the agency 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 response.

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

Abstract: The NPS Leasing Program allows any person or government entity to lease buildings and associated property administered by the Secretary of the Interior as part of the National Park System, under the authority of the Director of the NPS. A lease may not authorize an activity that could be authorized by a concessions contract or commercial use authorization. All leases must provide for the payment of fair market value rent. The Director may retain rental payments for park infrastructure needs and, in some cases, to provide administrative support of the leasing program.

The authority to collect information for the Leasing Program is derived from 54 U.S.C. 102101 *et seq.,* 54 U.S.C. 306121, and 36 CFR part 18. For competitive leasing opportunities, the regulations require the submission of proposals or bids by parties interested in applying for a lease. The regulations also require that the Director approve lease amendments, construction or demolition of structures, and encumbrances on leasehold interests.

We collect information from anyone who wishes to submit a bid or proposal to lease a property. The Director may issue a request for bids if the amount of rent is the only criterion for award of a lease. The Director issues a request for proposals when the award of a lease is based on selection criteria other than the rental rate. A request for proposals may be preceded by a request for qualifications to select a ''short list'' of potential offerors that meet minimum management, financial, and other qualifications necessary for submission of a proposal.

The Director may enter into negotiations for a lease with nonprofit organizations and units of government without soliciting proposals or bids. In those cases, the Director collects information from the other party regarding the planned use of the premises, potential modifications to the premises, and other information as necessary to support a decision on whether or not to enter into a lease.

Information is also collected from existing leaseholders who seek to:

- Sublet a leased property or assign the lease to a new lessee.
- Construct or demolish portions of a leased property.
- Amend a lease to change the type of activities permitted under the lease.
- Encumber (mortgage) the leased premises.

We use the information collected to evaluate offers, proposed subleases or assignments, proposed construction or demolition, the merits of proposed lease amendments, and proposed encumbrances. The completion times for each information collection requirement vary substantially depending on the complexity of the leasing opportunity.

Title of Collection: National Park Service Leasing Program, 36 CFR part 18.

OMB Control Number: 1024–0233.

Form Number: NPS Forms 10–352 through 10–355.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Individuals/households and businesses seeking to submit a bid or proposal to lease NPS property.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion.

Total Estimated Annual Nonhour Burden Cost: None.

Activity	Total annual responses	Completion time per response (hours)	Total annual burden hours
Requests for Qualifications/ Requests for Proposals/Requests for Bids—Simple	10	8	80
Requests for Qualifications/ Requests for Proposals—Complex	10	40	400
Lessee Construction/Demolition—Simple	1	12	12
Lessee Construction/Demolition—Complex	2	32	64
Lease Amendments	2	4	8
Lessee Encumbrances—Simple	2	8	16
Lessee Encumbrances—Complex	2	40	80
Subletting and Assignment of Leases—Simple	4	8	32
Subletting and Assignment of Leases—Complex	1	40	40
Totals	34	.....	732

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Phadrea Ponds,

Acting NPS Information Collection Clearance Officer, National Park Service.

[FR Doc. 2020–05528 Filed 3–17–20; 8:45 am]

BILLING CODE 4312–52–P

INTERNATIONAL TRADE COMMISSION

Section 337 Investigations; Notice of Commission Determination To Postpone All In-Person Section 337 Hearings Scheduled To Take Place Within the Next 60 Days

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to postpone all in-person hearings under section 337 of the Tariff Act of 1930 scheduled to take place within the next 60 days.

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. 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 section 337 investigations 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: In light of the ongoing Coronavirus (COVID–19) outbreak, the Commission has determined to postpone all section 337 in-person hearings scheduled to take place within the next 60 days. Commission Administrative Law Judges (''ALJ'') are directed to notify all affected parties and to schedule new dates for the hearings as appropriate. ALJs may otherwise conduct their investigations in accordance with their established procedures.

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: March 12, 2020.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2020–05569 Filed 3–17–20; 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 In Vitro Fertilization Products, and Components Thereof, and Products Containing the Same. DN 3440;* 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,* and will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000.

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 EMD Serono, Inc. on March 11, 2020. 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 in vitro fertilization products, and components thereof, and products containing the same. The complaint names as respondents: FastIVF c/o Domains by Proxy LLC of Scottsdale, AZ; Hermes Eczanesi of Turkey; and General Plastik Drug Stores of Turkey. The complainant requests that the Commission issue a general exclusion order, a limited exclusion order, cease desist orders and impose a bond upon respondents' 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. 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 and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to § 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the docket number (''Docket No. 3440'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures [1]). Persons with questions regarding filing should contact the Secretary (202–205–2000).

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: March 12, 2020.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2020–05530 Filed 3–17–20; 8:45 am]

BILLING CODE 7020–02–P

[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.*

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1165]

Certain Barcode Scanners, Scan Engines, Products Containing the Same, and Components Thereof; Notice of Commission Decision Not To Review an Initial Determination Terminating the Investigation Based on Settlement; Termination of the Investigation

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'') (Order No. 26) of the presiding administrative law judge (''ALJ'') terminating the investigation based on settlement. The investigation is terminated.

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 are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. 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 July 2, 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 Honeywell International, Inc. of Morris Plains, New Jersey; Hand Held Products, Inc. of Fort Mill, South Carolina; and Metrologic Instruments, Inc. of Fort Mill, South Carolina. *See* 84 FR 31619–20 (July 2, 2019). The complaint, as supplemented, alleges violations 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 barcode scanners, scan engines, products containing the same, and components thereof, by reason of infringement of certain claims of U.S. Patent Nos. 9,465,970; 8,978,985; 7,148,923; 7,527,206; 9,659,199; and 7,159,783. *See id.* at 31619. The notice of investigation names the following respondents: Opticon, Inc. of Renton, Washington; Opticon Sensors Europe B.V. of Hoofddorp, The Netherlands; OPTO Electronics Co., Ltd. of Warabi, Japan; and Hokkaido Electronic Industry Co., Ltd. of Ashibetsu-shi, Japan. *See id.* The Office of Unfair Import Investigations is not a party to the investigation.

On February 18, 2020, the parties filed a joint motion to terminate the investigation based on settlement. On February 27, 2020, the ALJ issued the subject ID (Order No. 26) granting the joint motion. In accordance with Commission Rule 210.21(b)(1), 19 CFR 210.21(b)(1), the motion includes redacted and unredacted copies of the settlement agreement. *See* ID at 3. In addition, as noted in the ID, the motion includes a statement that ''there are no other agreements, written or oral, express or implied, between [the parties] concerning the subject matter of this Investigation.'' *See id.* Furthermore, in accordance with Commission Rule 210.50(b)(2), 19 CFR 210.50(b)(2), the ID finds that ''termination of this Investigation on the basis of the Settlement Agreement would not be contrary to the public health and welfare, competitive conditions in the U.S. economy, the production of like or directly competitive articles in the United States, or U.S. consumers.'' *Id.* The ID further finds that ''termination of this Investigation is in the public

interest and will conserve public and private resources.'' *Id.* No petition for review of the subject ID was filed.

The Commission has determined not to review the subject ID. The investigation is terminated.

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: March 13, 2020.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2020–05622 Filed 3–17–20; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Notice of Proposed Settlement Agreement and Draft Restoration Plan Under the Comprehensive Environmental Response, Compensation and Liability Act and Clean Water Act

Notice is hereby given that the United States of America, on behalf of the Department of the Interior (''DOI'') acting through the Fish and Wildlife Service and the Commonwealth of Virginia, acting through its Secretary of Natural Resources (collectively ''Trustees''), are providing an opportunity for public comment on a proposed Settlement Agreement (''Settlement Agreement'') among the Trustees and Nutrien Ag Solutions (f/k/a Crop Production Services). The Trustees are also providing notice of an opportunity for public comment on a draft Restoration Plan (''draft Restoration Plan'').

The settlement resolves the civil claims of the Trustees against Nutrien Ag Solutions (''Nutrien'') arising under their natural resource trustee authority under the Comprehensive Environmental Response, Compensation, and Liability Act, and applicable state law for injury to, impairment of, destruction of, and loss of use of natural resources as a result of a July 29, 2017 release of approximately 165 gallons of Termix 5301 at or from the Nutrien facility located at 218 Simmons Drive in Cloverdale, Virginia (''Release''). The Release occurred when a container leaked into a stormwater culvert which discharged into Tinker Creek.

Under the proposed Settlement Agreement, Nutrien agrees to pay $385,000 to the DOI Natural Resource Damage Assessment and Restoration Fund to be used to restore, replace, rehabilitate, or acquire the equivalent of those resources injured by the Release and compensate the public for lost recreational opportunities, as proposed in the draft Restoration Plan. In addition, Nutrien agrees to pay $40,000 to the Trustees for restoration planning and oversight costs. Nutrien will receive from the Trustees a covenant not to sue for natural resource damages under CERCLA, the Clean Water Act, and applicable state laws.

In accordance with the CERCLA and the National Environmental Policy Act, the Trustees have also written a draft Restoration Plan/Environmental Assessment that describes proposed alternatives for restoring the natural resources and natural resource services injured by the Release. The two preferred restoration alternatives selected by the Trustees in the draft Plan are (1) Fish Passage Improvements through the removal of impediments in Tinker Creek; and (2) Recreational Fishing Improvements through one time fish re-stocking and hosting a children's fishing day.

The publication of this notice opens a period for public comment on the proposed Settlement Agreement and draft Restoration Plan. Comments on the proposed Settlement Agreement should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to the Tinker Creek Release Settlement Agreement, D.J. Ref. No. 90–5–1–1–11891. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the Settlement Agreement may be examined and downloaded at this Justice Department website: *https://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the Settlement Agreement upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $3.00 (25 cents per page reproduction cost) payable to the United States Treasury.

Comments on the draft Restoration Plan may be submitted to the Trustees either by email or by mail:

To submit comments:	*Send them to:*
By email	*Susan_Lingenfelser@fws.gov.*
By mail	USFWS Virginia Field Office, 6669 Short Lane, Gloucester, VA 23061, Attn: Tinker Creek Restoration Plan.

All comments must be submitted no later than thirty (30) days after the publication date of this notice. During the public comment period, a copy of the draft Restoration Plan will be available electronically at *https://www.cerc.usgs.gov/orda_docs/DocHandler.ashx?task=get&ID=5859.* A copy of the draft Restoration Plan may also be examined at the Virginia Ecological Services Field Office. Arrangements to view the documents must be made in advance by contacting Susan Lingenfelser at (804) 824–2415.

Jeffrey Sands,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2020–05595 Filed 3–17–20; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Application for Waiver of Surface Sanitary Facilities' Requirements (Pertaining to Coal Mines)

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Mine Safety and Health Administration (MSHA)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before April 17, 2020.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/*

PRAMain. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) if the information will be processed and used in a timely manner; (3) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (4) ways to enhance the quality, utility and clarity of the information collection; and (5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Frederick Licari by telephone at 202–693–8073, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: Title 30 CFR 71.400 through 71.402 and 75.1712–1 through 75.1712–3 require coal mine operators to provide bathing facilities, clothing change rooms, and sanitary flush toilet facilities in a location that is convenient for use of the miners. If the operator is unable to meet any or all of the requirements, the operator may apply for a waiver. Title 30 CFR 71.403, 71.404, 75.1712–4, and 75.1712–5 provide procedures by which an operator may apply for and be granted a waiver. Applications must be submitted to the MSHA District Manager for the district in which the mine is located and must contain the name and address of the mine operator, name and location of the mine, and a detailed statement of the grounds on which the waiver is requested. Waivers for surface mines may be granted by the District Manager for a period not to exceed one year. If the waiver is granted, surface mine operators may apply for annual extensions of the approved waiver. Waivers for underground mines may be granted by the District Manager for the period of time requested by the underground mine operator as long as the circumstances that were used to justify granting the waiver remain in effect. Waivers are not transferable to a successor coal mine operator. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on January 2, 2020 (85 FR 134).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–MSHA.

Title of Collection: Application for Waiver of Surface Sanitary Facilities' Requirements (Pertaining to Coal Mines).

OMB Control Number: 1219–0024.

Affected Public: Private Sector: Businesses or other for-profits.

Total Estimated Number of Respondents: 525.

Total Estimated Number of Responses: 525.

Total Estimated Annual Time Burden: 232 hours.

Total Estimated Annual Other Costs Burden: $2,625.

Authority: 44 U.S.C. 3507(a)(1)(D).

Dated: March 12, 2020.

Frederick Licari,

Departmental Clearance Officer.

[FR Doc. 2020–05607 Filed 3–17–20; 8:45 am]

BILLING CODE 4510–43–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Slope and Shaft Sinking Plans (Pertains to Surface Work Areas of Underground Coal Mines)

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Mine Safety and Health Administration (MSHA)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before April 17, 2020.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) if the information will be processed and used in a timely manner; (3) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (4) ways to enhance the quality, utility and clarity of the information collection; and (5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Frederick Licari by telephone at 202–693–8073, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: Section 103(h) of the Federal Mine Safety and Health Act of 1977 (Mine Act), 30 U.S.C. 813(h), authorizes MSHA to collect information necessary to carry out its duty in protecting the safety and health of miners. Further, section 101(a) of the Mine Act, 30 U.S.C. 811, authorizes the Secretary of Labor to develop, promulgate, and revise as may be appropriate, improved mandatory health or safety standards for the protection of life and prevention of injuries in coal and metal and nonmetal mines. Title 30 CFR 77.1900 requires underground coal mine operators to submit for approval a plan that will provide for the safety of workmen in each slope or shaft that is commenced or extended from the surface to the underground coal mine. Each slope or shaft sinking operation is unique in that each operator uses different methods and equipment and encounters different geological strata which make it impossible for a single set of regulations to ensure the safety of the miners under all circumstances. This makes an individual slope or shaft sinking plan

necessary. The plan must be consistent with prudent engineering design. Plans include the name and location of the mine; name and address of the mine operator; a description of the construction work and methods to be used in construction of the slope or shaft, and whether all or part of the work will be performed by a contractor; the elevation, depth and dimensions of the slope or shaft; the location and elevation of the coalbed; the general characteristics of the strata through which the slope or shaft will be developed; the type of equipment which the operator proposes to use; the system of ventilation to be used; and safeguards for the prevention of caving during excavation. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on January 2, 2020 (85 FR 141).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–MSHA.

Title of Collection: Slope and Shaft Sinking Plans (Pertains to Surface Work Areas of Underground Coal Mines).

OMB Control Number: 1219–0019.

Affected Public: Private Sector: Businesses or other for-profits.

Total Estimated Number of Respondents: 35.

Total Estimated Number of Responses: 91.

Total Estimated Annual Time Burden: 1,820 hours.

Total Estimated Annual Other Costs Burden: $55.

Authority: 44 U.S.C. 3507(a)(1)(D).

Dated: March 12, 2020.

Frederick Licari,

Departmental Clearance Officer.

[FR Doc. 2020–05614 Filed 3–17–20; 8:45 am]

BILLING CODE 4510–43–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; The Family and Medical Leave Act of 1993, as Amended

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Wage and Hour Division (WHD)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before April 17, 2020.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) if the information will be processed and used in a timely manner; (3) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (4) ways to enhance the quality, utility and clarity of the information collection; and (5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Frederick Licari by telephone at 202–693–8073, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: The Family and Medical Leave Act of 1993 (FMLA), 29 U.S.C. 2601, requires private sector employers who employ 50 or more employees, all public and private elementary schools, and all public agencies to provide up to 12 weeks of unpaid, job-protected leave during any 12-month period to eligible employees for certain family and medical reasons (for birth of a son or daughter and to care for the newborn child; for placement with the employee of a son or daughter for adoption or foster care; to care for the employee's spouse, son, daughter, or parent with a serious health condition; because of a serious health condition that makes the employee unable to perform the functions of the employee's job; and to address qualifying exigencies arising out of the deployment of the employee's spouse, son, daughter, or parent to covered active duty in the military), and up to 26 weeks of unpaid, job protected leave during a single 12-month period to care for a covered servicemember with a serious injury or illness who is the spouse, son, daughter, parent, or next of kin to the employee.

WHD created optional use forms: WHD Publication 1420, WH–380–E, WH–380–F, WH–381, WH–382, WH–384, WH–385, and WH–385–V to assist employers and employees in meeting their FMLA third-party notification obligations. WHD Publication 1420 allows employers to satisfy the general notice requirement. See § 825.300(a). Form WH–380–E allows an employee requesting FMLA leave for his or her own serious health condition to satisfy the statutory requirement to furnish, upon the employer's request, appropriate certification (including a second or third opinion and recertification) to support the need for leave for the employee's own serious health condition. See § 825.305(a). Form WH–380–F allows an employee requesting FMLA leave for a family member's serious health condition to satisfy the statutory requirement to furnish, upon the employer's request, appropriate certification (including a second or third opinion and recertification) to support the need for leave for the family member's serious health condition. See § 825.305(a). Form WH–381 allows an employer to satisfy the regulatory requirement to provide employees taking FMLA leave with written notice detailing specific expectations and obligations of the employee and explaining any consequences of a failure to meet these obligations. See § 825.300(b) and (c). Form WH–382 allows an employer to meet its obligation to designate leave as FMLA-qualifying. See § 825.301(a). Form WH–384 allows an employee requesting FMLA leave based on a qualifying exigency to satisfy the statutory requirement to furnish, upon the employer's request, appropriate certification to support leave for a qualifying exigency. See § 825.309. Form WH–385 allows an employee

requesting FMLA leave based on an active duty covered servicemember's serious injury or illness to satisfy the statutory requirement to furnish, upon the employer's request, a medical certification from an authorized health care provider. See § 825.310. Form WH–385–V allows an employee requesting leave based on a veteran's serious injury or illness to satisfy the statutory requirement to furnish, upon the employer's request, a medical certification from an authorized health care provider. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on August 5, 2019 (84 FR 38061).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–WHD.

Title of Collection: The Family and Medical Leave Act of 1993, As Amended.

OMB Control Number: 1235–0003.

Affected Public: Businesses or other for-profits, not-for-profit institutions, Farms, State, Local, or Tribal Government.

Total Estimated Number of Respondents: 6,888,800.

Total Estimated Number of Responses: 79,357,736.

Total Estimated Annual Time Burden: 8,307,116 hours.

Total Estimated Annual Other Costs Burden: $185,726,276.

Authority: 44 U.S.C. 3507(a)(1)(D).

Dated: March 12, 2020.

Frederick Licari,

Departmental Clearance Officer.

[FR Doc. 2020–05613 Filed 3–17–20; 8:45 am]

BILLING CODE 4510–27–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2020–0003]

Advisory Committee on Construction Safety and Health (ACCSH): Notice of Meetings

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice of ACCSH and ACCSH Workgroup meetings.

SUMMARY: The Advisory Committee on Construction Safety and Health (ACCSH) will meet April 29, 2020, in Washington, DC. In conjunction with the ACCSH meeting, ACCSH Workgroups will meet April 28, 2020.

DATES: *ACCSH meeting:* ACCSH will meet from 9 a.m. to 4 p.m., ET, Wednesday, April 29, 2020.

ACCSH Workgroup meetings: Prior to the full Committee meeting, ACCSH Workgroups will meet Tuesday, April 28, 2020. (For Workgroup meeting times, see the schedule under ''Workgroup Meetings'' in the **SUPPLEMENTARY INFORMATION** section of this notice.)

ADDRESSES:

Submission of comments and requests to speak: Submit comments and requests to speak at the ACCSH and ACCSH Workgroup meetings by Friday, April 17, 2020, identified by the docket number for this **Federal Register** notice (Docket No. OSHA–2020–0003), using one of the following methods:

Electronically: You may submit comments, including attachments, electronically at: *http://www.regulations.gov,* the Federal eRulemaking Portal. Follow the online instructions for submitting comments.

Facsimile: If your comments, including attachments, do not exceed 10 pages, you may fax them to the OSHA Docket Office at (202) 693–1648.

Regular mail, express mail, hand delivery, and messenger or courier service: You may submit comments and attachments to the OSHA Docket Office, Docket No. OSHA–2020–0003, Occupational Safety and Health Administration, U.S. Department of Labor, Room N–3653, 200 Constitution Avenue NW, Washington, DC 20210. Deliveries (express mail, hand (courier) delivery, and messenger service) are accepted during the OSHA Docket Office's normal business hours, Monday–Friday, 10:00 a.m. to 3:00 p.m., ET.

Instructions: All submissions must include the agency name and the OSHA docket number for this **Federal Register** notice (Docket No. OSHA–2020–0003). Because of security-related procedures, submissions by regular mail may result in a significant delay in receipt. Please contact the OSHA Docket Office for information about security procedures for making submissions by express mail, hand (courier) delivery, and messenger service.

Requests for special accommodations: Please submit requests for special accommodations for this ACCSH meeting by Friday, April 17, 2020, to Ms. Gretta Jameson, OSHA, Office of Communications, Room N–3647, U.S. Department of Labor, 200 Constitution Avenue NW, Washington, DC 20210; telephone: (202) 693–1999; email: *jameson.grettah@dol.gov.*

FOR FURTHER INFORMATION CONTACT:

For press inquiries: Mr. Frank Meilinger, Director, OSHA Office of Communications, U.S. Department of Labor; telephone (202) 693–1999; email: *meilinger.francis2@dol.gov.*

For general information about ACCSH: Mr. Damon Bonneau, OSHA, Directorate of Construction, U.S. Department of Labor; telephone (202) 693–2183; email: *bonneau.damon@dol.gov.*

For copies of this ***Federal Register*** * * * Electronic copies of this **Federal Register** Notice are available at: *http://www.regulations.gov.* This notice, as well as news releases and other relevant information, are also available at OSHA's web page at *www.osha.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

ACCSH advises the Secretary of Labor and the Assistant Secretary of Labor for Occupational Safety and Health (Assistant Secretary) in the formulation of standards affecting the construction industry, and on policy matters arising in the administration of the safety and health provisions under the Contract Work Hours and Safety Standards Act (Construction Safety Act (CSA)) (40 U.S.C. 3701 *et seq.*) and the Occupational Safety and Health Act of 1970 (OSH Act) (29 U.S.C. 651 *et seq.*) (29 CFR 1911.10 and 1912.3). In addition, the OSH Act and CSA require the Assistant Secretary to consult with ACCSH before the agency proposes any occupational safety and health standard affecting construction activities (29 CFR 1911.10; 40 U.S.C. 3704).

ACCSH operates in accordance with the CSA, the OSH Act, the Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2), and regulations issued pursuant to those statutes (29 CFR part 1912, 41 CFR part 102–3). ACCSH generally meets two times a year.

II. Meeting Information

Workgroup Meetings

Attending the meetings: The following ACCSH workgroups will meet Tuesday, April 28, 2020, at the U.S. Department of Labor, 200 Constitution Avenue NW, Washington, DC 20210. The workgroups will meet in Conference Rooms N–3437 A, B, C, and D. Due to heighten security measures, all potential attendees are asked to submit their name to Ms. Jameson (see ''Requests for special accommodations'' in the **ADDRESSES** section of this notice) by Friday, April 17, 2020. Meeting attendees must use the visitor's entrance located at 3rd & C Streets NW.

• Education, Training, and Outreach Workgroup: 9 a.m. to 12 p.m., ET

Meeting agenda:
1. Trench Safety.
2. Fall Prevention.

• Emerging and Current Issues Workgroup: 1 to 4 p.m., ET

Meeting agenda:
1. Opioids.
2. Suicides in construction.

ACCSH workgroup meetings are open to the public. For additional information on ACCSH workgroup meetings or participating in them, please contact Mr. Bonneau (see ''*For general information about ACCSH*'' in the **FOR FURTHER INFORMATION CONTACT** section of this notice).

ACCSH Full Committee Meeting

Attending the meeting: ACCSH will meet from 9 a.m. to 4 p.m., ET, Wednesday, April 29, 2020, at the U.S. Department of Labor, 200 Constitution Avenue NW, Washington, DC 20210. The Committee will meet in Conference Rooms N–3437 A, B, C and D. Due to heighten security measures, all potential attendees are asked to submit their name to Ms. Jameson (see ''*Requests for special accommodations*'' in the **ADDRESSES** section of this notice) by Friday, April 17, 2020. Meeting attendees must use the visitor's entrance located at 3rd & C Streets NW.

Meeting agenda: The tentative agenda for this meeting includes:

• Principal Deputy Assistant Secretary's agency update and remarks;
• Directorate of Construction update;
• Directorate of Standards and Guidance update;
• ACCSH's consideration of, and recommendation on, the following proposals:

—Updating the design and construction requirements of the powered industrial trucks standards by adding an incorporation by reference to the applicable provisions of the most recent ANSI/ITSDF consensus standards;
—Updating the Hazard Communication Standard to maintain alignment with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS);

• Silica in Construction update;
• ACCSH workgroup reports; and,
• Public Comment Period.

Requests to speak and speaker presentations: Attendees who wish to address ACCSH at either the full committee meeting or the workgroup meetings must submit a request to speak, as well as any written or electronic presentation, by Friday, April 17, 2020, using one of the methods listed in the **ADDRESSES** section of this notice. The request must state:

• The amount of time requested to speak;
• The interest you represent (*e.g.,* business, organization, affiliation), if any; and
• A brief outline of your presentation.

PowerPoint presentations and other electronic materials must be compatible with PowerPoint 2010 and other Microsoft Office 2010 formats.

Alternately, at the meetings, you may request to address ACCSH briefly by signing the public-comment request sheet and listing the topic(s) you will address. You also must provide 20 hard copies of any materials, written or electronic, you want to present to ACCSH.

At his discretion, the ACCSH Chair may grant requests to address ACCSH as time and circumstances permit.

Docket: OSHA will place comments, requests to speak, and speaker presentations, including any personal information you provide, in the public docket without change, and those documents may be available online at: *http://www.regulations.gov.* Therefore, OSHA cautions interested parties about submitting personal information such as Social Security Numbers and birthdates. OSHA also places in the public docket the meeting transcript, meeting minutes, documents presented at the meeting, and other documents pertaining to the ACCSH and ACCSH Workgroup meetings. These documents are available online at: *http://www.regulations.gov.* To read or download documents in the public docket for these ACCSH and ACCSH Workgroup meetings, go to Docket No. OSHA–2020–0003 at: *http://www.regulations.gov.* All documents in the public docket are listed in the index; however, some documents (*e.g.,* copyrighted material) are not publicly available to read or download through *http://www.regulations.gov.* All submissions are available for inspection and, when permitted, copying at the OSHA Docket Office at the above address. For information on using *http://www.regulations.gov* to make submissions or to access the docket, click on the ''Help'' tab at the top of the homepage. Contact the OSHA Docket Office for information about materials not available through that website and for assistance in using the internet to locate submissions and other documents in the docket.

Authority and Signature

Loren Sweatt, Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health, authorized the preparation of this notice under the authority granted by 29 U.S.C. 655(b)(1) and 656(b), 5 U.S.C. App. 2, Secretary of Labor's Order No. 1–2012 (77 FR 3912), and 29 CFR part 1912.

Signed at Washington, DC, on March 12, 2020.

Loren Sweatt,

Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2020–05615 Filed 3–17–20; 8:45 am]

BILLING CODE 4510–26–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (20–033)]

National Space Council Users' Advisory Group; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the National Aeronautics and Space Administration (NASA) announces a meeting of the National Space Council Users' Advisory Group (UAG). This will be the fifth meeting of the UAG.

DATES: Monday, March 30, 2020, from 10 a.m.–1 p.m., Mountain Time (MT).

ADDRESSES: The Broadmoor Hotel, International Center Ballroom, 1 Lake Avenue, Colorado Springs, Colorado 80906.

FOR FURTHER INFORMATION CONTACT: Mr. James Joseph Miller, UAG Designated Federal Officer/Executive Secretary, NASA Headquarters, Washington, DC 20546, (202) 358–4417 or *jj.miller@nasa.gov.*

SUPPLEMENTARY INFORMATION: This meeting will be open to the public up to the capacity of the meeting room. For

security purposes, pre-registration is required to attend this event in person. For in-person attendance, pre-register online by no later than 1:00 p.m. on Friday, March 27, 2020 using the following web link: *https://www.launchsquid.com/register/2509.* Please bring pre-registration confirmation and valid government identification when checking-in prior to this event. This meeting is also available telephonically and via WebEx. You must use a touch-tone phone to participate in this meeting. Any interested person may dial the toll-free number 1–844–467–4685 and then the numeric passcode 106724, followed by the # sign. NOTE: when dialing in, please ''mute'' your phone.

To join via WebEx, the link is: *https://nasaenterprise.webex.com,* meeting number is 908 651 713, and the meeting password is hYqt2eBp$43 (case sensitive).

The agenda for the meeting will include the following:

—Opening Remarks and Meeting Objectives by UAG Chair
—Expert Presentations on ''Space Economy Stimulation Through Deregulation'' and ''Artemis Architecture Update,'' per Subcommittee Focus Areas
—Reports and Updates from UAG Subcommittees:
- Exploration and Discovery
- National Security Space
- Technology and Innovation
- Economic Development/Industrial Base
- Outreach and Education
- Space Policy and International Engagement

—Preliminary Deliberations on any Findings and Recommendations
—Other UAG Business and Work Plan Schedule; Closing Remarks

Summary: As noted above, in-person attendees will be requested to show pre-registration confirmation, valid government identification, and sign a register prior to entrance to the meeting.

It is imperative that the meeting be held on this date to meet the scheduling availability of key participants.

For further information and any UAG meeting updates, visit the UAG website at: *https://www.nasa.gov/content/national-space-council-users-advisory-group.*

Patricia Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 2020–05538 Filed 3–17–20; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (20–034)]

NASA Advisory Council; Technology, Innovation and Engineering Committee; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting. [*Note:* This is a revised and resubmitted **Federal Register** Notice to inform the public that the subject meeting will now be virtual only, and has a new time.]

REF: Federal Register/Vol. 85, No. 41/ Monday, March 2, 2020/Notices; page 12347.

SUMMARY: In accordance with the Federal Advisory Committee Act, as amended, the National Aeronautics and Space Administration (NASA) announces a meeting of the Technology, Innovation and Engineering Committee of the NASA Advisory Council (NAC). This Committee reports to the NAC. This meeting was announced in the **Federal Register** on March 2, 2020 (see reference above).

DATES: Thursday, March 19, 2020, 11:00 a.m.–5:00 p.m., Eastern Time. (Note new time)

ADDRESSES: Meeting will now be virtual only, see dial-in and WebEx information below under **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Mr. Mike Green, Designated Federal Officer, Space Technology Mission Directorate, NASA Headquarters, Washington, DC 20546, (202) 358–4710, or *g.m.green@nasa.gov.*

SUPPLEMENTARY INFORMATION: As noted above, this meeting will be available telephonically and by WebEx only. You must use a touch-tone phone to participate in this meeting. Any interested person may dial the toll-free access number 1–844–467–6272 and enter the numeric participant passcode 102421 followed by the # sign. The WebEx link is *https://nasaenterprise.webex.com,* the meeting number is 903 769 393, and the password is n@cTIE031920. *Note:* If dialing in, please ''mute'' your telephone. The agenda for the meeting includes the following topics:

—Space Technology Mission Directorate Update
—FY 2021 Budget Proposal and Update
—Space Technology on International Space Station Update
—Lunar Surface Innovation Initiative Update
—Flight Opportunities and Small Spacecraft Technology Program Updates
—Office of the Chief Engineer Update
—Overview of Processes to Evaluate Technology Implementation

It is imperative that this meeting be held on this day to accommodate the scheduling priorities of the key participants.

Patricia Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 2020–05654 Filed 3–17–20; 8:45 am]

BILLING CODE 7510–13–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–275 and 50–323; NRC–2020–0054]

Pacific Gas and Electric Company; Diablo Canyon Nuclear Power Station, Units 1 and 2; Cancellation of Public Meeting

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of receipt; public meeting; and request for comment.

SUMMARY: On February 21, 2020, the U.S. Nuclear Regulatory Commission (NRC) solicited comments on the Post-Shutdown Decommissioning Activities Report (PSDAR) for the Diablo Canyon Nuclear Power Plant (Diablo Canyon), Units 1 and 2. The NRC had planned to hold a public meeting to discuss the PSDAR and receive comments. The public meeting was originally scheduled to be held on March 19, 2020. The NRC has decided to reschedule the public meeting at a later date due to concerns with the Coronavirus: COVID–19.

DATES: Submit comments by June 22, 2020. Comments received after this date will be considered, if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

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

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2020–0054. Address questions about NRC dockets IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Office of Administration, Mail Stop: TWFN–7–

A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Balwant K. Singal, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–3016; email: *Balwant.Singal@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2020–0054 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2020–0054.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The Diablo Canyon, Units 1 and 2, PSDAR is available in ADAMS under Accession No. ML19338F173.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2020–0054 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as entering the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

II. Discussion

On February 21, 2020 (85 FR 10200), the NRC solicited comments on the PSDAR for Diablo Canyon, Units 1 and 2. The PSDAR includes a description of the planned decommissioning activities, a proposed schedule for their accomplishment, cost summary from the Decommissioning Cost Estimate, and a discussion that provides the basis for concluding that the environmental impacts associated with the site-specific decommissioning activities will be bounded by appropriate, previously issued generic and plant-specific environmental impact statements.

The NRC is requesting public comments on the PSDAR for Diablo Canyon, Units 1 and 2. The NRC had planned to conduct a public meeting to discuss the PSDAR and receive comments on Thursday, March 19, 2020, from 6:00 p.m. until 8:00 p.m., at the Board of Supervisors Chambers, County Government Center, 1055 Monterey Street, San Luis Obispo, California 93408. However, the NRC has decided to reschedule the meeting to a later date due to concerns with the Coronavirus: COVID–19. The comment period due date remains the same. The NRC requests that comments be submitted as noted in the **ADDRESSES** section of this document in writing by June 22, 2020.

Dated at Rockville, Maryland, this 12th day of March 2020.

For the Nuclear Regulatory Commission.

Jennifer L. Dixon-Herrity,

Chief, Plant Licensing Branch IV, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2020–05564 Filed 3–17–20; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–348, 50–366, 50–321, 50–366, 50–424, and 50–425; NRC–2020–0068]

Southern Nuclear Operating Company; Farley Nuclear Plant, Units 1 and 2; Hatch Nuclear Power Plant, Units 1 and 2; and Vogtle Electric Generating Plant, Units 1 and 2

AGENCY: Nuclear Regulatory Commission.

ACTION: Exemption; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has issued exemptions in response to an October 31, 2019, request from Southern Nuclear Operating Company (SNC). The exemptions would allow SNC to submit changes to the Quality Assurance Topical Report that do not reduce commitments on a 24-month calendar schedule.

DATES: The exemption was issued on March 12, 2020.

ADDRESSES: Please refer to Docket ID NRC–2020–0068 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2020–0068. Address questions about NRC docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The exemption request dated October 31, 2019, ''Quality Assurance Topical Report Submittal Request for Schedular Exemption—10 CFR 50.54(a)(3)'' is available in ADAMS under Accession No. ML19304C213.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: John G. Lamb, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington DC 20555–0001; telephone: 301–415–3100, email: *John.Lamb@nrc.gov.*

SUPPLEMENTARY INFORMATION: The text of the exemption is attached.

Dated at Rockville, Maryland, this 13th day of March, 2020.

For the Nuclear Regulatory Commission.

John G. Lamb,

Senior Project Manager, Plant Licensing Branch II–1, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

Attachment Exemption

Nuclear Regulatory Commission

Docket Nos. 50–348, 50–364, 50–321, 50–366, 50–424, and 50–425, Southern Nuclear Operating Company, Joseph M. Farley Nuclear Power Plant, Units Nos. 1 and 2; Edwin I. Hatch Nuclear Plant, Units Nos. 1 and 2; and Vogtle Electric Generating Plant, Unit Nos. 1 and 2, Exemption

I. Background

Southern Nuclear Operating Company (SNC, the licensee) is the holder of the Renewed Facility Operating Licenses (RFOLs) Nos. NPF–2 and NPF–8 for Joseph M. Farley Nuclear Plant, Unit Nos. 1 and 2 (Farley), which consist of two pressurized-water reactors (PWRs) located in Houston County, Alabama; DPR–57 and NPF–5 for Edwin I. Hatch Nuclear Plant, Unit Nos. 1 and 2 (Hatch), which consist of two boiling-water reactors (BWRs) located in Appling County, Georgia; and NPF–68 and NPF–81 for Vogtle Electric Generating Plant, Unit Nos. 1 and 2 (Vogtle), which consist of two PWRs located in Burke County, Georgia. The RFOLs provide, among other things, that the facilities are subject to all the rules, regulations, and orders of the U.S. Nuclear Regulatory Commission (NRC, Commission) now or hereafter in effect.

II. Request/Action

Title 10 of the *Code of Federal Regulations* (10 CFR), Section 50.54(a)(3), requires that changes to the quality assurance program description that do not reduce commitments must be submitted to the NRC in accordance with the reporting requirements of 10 CFR 50.71(e).

The regulation at 10 CFR 50.71(e)(4) requires that revisions to the final safety analysis report (FSAR) be submitted annually or six months after a refueling outage, provided the interval between updates does not exceed 24 months. SNC's exemption request proposes that changes to the quality assurance program that do not reduce commitments be submitted on a 24-month calendar schedule, not to exceed 24 months from the previous submittal. The exemptions would apply to each of the plants identified above.

III. Discussion

Pursuant to 10 CFR 50.12, the Commission may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of 10 CFR part 50 when (1) the exemptions are authorized by law, will not present an undue risk to public health and safety, and are consistent with the common defense and security; and (2) any of the special circumstances listed in 10 CFR 50.12(a)(2) are present. The special circumstances as stated in 10 CFR 50.12(a)(2), include, among other things that ''Application of the regulation in the particular circumstances would not serve the underlying purpose of the rule or is not necessary to achieve the purpose of the rule.''

Operational quality assurance programs are generally described in Chapter 17.2 of a licensee's Updated Safety Analysis Report (USAR) or, alternately, in a topical report incorporated into the USAR by reference. SNC's quality assurance program, described in the Quality Assurance Topical Report (QATR), is common to the 6 units requesting the exemptions. Compliance with 10 CFR 50.54(a)(3) and 10 CFR 50.71(e)(4) would require these changes to be submitted annually or after a refueling outage for each of the licensee's units.

A. The Exemption Is Authorized by Law

In accordance with 10 CFR 50.12, the NRC may grant an exemption from the requirements of 10 CFR part 50, if the exemption is authorized by law. As stated in 10 CFR 50.71(e)(4), subsequent revisions of the FSAR must be filed annually or 6 months after each refueling outage provided the interval between successive updates does not exceed 24 months.

SNC stated that changes to the QATR will be reviewed through the existing applicable administrative and programmatic control processes to ensure QATR changes are evaluated and implemented properly. Therefore, the NRC staff finds that the alternative reporting cycle of 24 months for submitting QATR changes specified under 10 CFR 50.54(a)(3) provides adequate control. Further, the exemptions propose that changes to the quality assurance program that do not reduce commitments be submitted on a 24-month calendar schedule, not to exceed the 24-month limit specified in 10 CFR 50.71(e)(4). Therefore, the NRC staff finds that this exemption request is authorized by law, because granting the licensee's proposed exemptions will not result in a violation of the Atomic Energy Act of 1954, as amended, or the Commission's regulations.

B. The Exemption Presents No Undue Risk to Public Health and Safety

The licensee stated that the proposed exemptions will not alter the manner in which changes to the common QATR are evaluated and that there is no reduction in commitment. SNC stated that changes to the QATR will be reviewed through the existing applicable administrative and programmatic control processes to ensure that QATR changes are evaluated and implemented properly. The regulation 10 CFR 50.54(a)(3) requires licensees to provide their QATRs periodically per 10 CFR 50.71(e) to assure that the NRC has the latest material developed by SNC. In 10 CFR 50.71(e)(4), the NRC has determined that an update frequency not to exceed 24 months between successive updates to be acceptable for periodic submissions of the QATR. The exemptions propose that changes to the QATR that do not reduce commitments be submitted on a 24-month calendar schedule, not to exceed 24 months from the previous submittal. Therefore, the NRC staff finds that the proposed exemptions provide an equivalent level of protection to the existing requirements. Further, QA Program changes that are not considered to be reductions in commitment involve, among other things, administrative improvements and clarifications, spelling corrections, punctuation, or editorial items. Therefore, the NRC staff finds that the changes specified in 10 CFR 50.54(a)(3) are administrative and routine in nature.

Also, based on its review of the exemption request, the NRC staff concludes that the requested exemptions would not result in any significant reduction in the effectiveness of the QA program implemented by SNC. Based on the foregoing reasons, the NRC staff concludes that the proposed exemption would not present an undue risk to the public health and safety.

C. The Exemption Is Consistent With the Common Defense and Security

This exemption requests periodic updates of the SNC QATR to be

submitted every 24 months, not to exceed 24 months from the previous submittal. Upon issuance of the exemptions, the regulatory requirement that an update be submitted annually or within six months following each plant's refueling outage would not be retained. Since the underlying intent of the regulation is to ensure that QATR changes that do not reduce the level of commitment are periodically submitted to the NRC, and the required schedule per 10 CFR 50.71(e)(4) allows for 24 months between periodic submittals, the NRC staff finds that processing more frequent changes to the common QATR is not an effective or efficient allocation of resources nor is it necessary to achieve the purpose of the rule. Moreover, as noted above, the proposed exemptions provide an equivalent level of protection to the existing regulation in that changes to the QATR that do not reduce commitments must be submitted on a schedule not to exceed 24 months of the SNC QATR from the previous submittal. Therefore, the common defense and security are not affected by this exemption request.

D. Special Circumstances

The regulation under 10 CFR 50.12(a)(2) states, in part, that ''[t]he Commission will not consider granting an exemption unless special circumstances are present,'' and identifies, in 10 CFR 50.12(a)((i)–(vi), when special circumstances are present. The NRC staff determined that special circumstances are present. Special circumstances, in accordance with 10 CFR 50.12(a)(ii), are present whenever application of the regulation in the particular circumstances would not serve the underlying purpose of the rule or is not necessary to achieve the underlying purpose of the rule.

As stated in 10 CFR 50.71(e)(4), subsequent revisions to the FSAR must be filed annually or 6 months after each refueling outage provided the interval between successive updates does not exceed 24 months. The underlying purpose of the rule is to ensure that periodic submittals required under 10 CFR 50.54(a)(3) would allow the NRC staff to provide regulatory oversight to changes to the licensee's QA program, and to ensure that the changes are consistent with the regulations. The exemptions requested by SNC only extend the reporting period, and do not exceed the 24-month time period between successive updates established by 10 CFR 50.71(e). Thus, SNC would still provide updates of their QATR to the NRC periodically every 24 months, allowing periodic NRC oversight of changes to the licensee's QA program. Therefore, the NRC staff finds that application of the regulation in this particular circumstance is not necessary to achieve the underlying purpose of the rule.

Accordingly, the NRC staff concludes that, pursuant to 10 CFR 50.12(a)(2)(ii), special circumstances are present.

E. Environmental Considerations

Pursuant to 10 CFR 51.22(b) and 10 CFR 51.22(c)(25), the granting of an exemption from the requirements of any regulation in Chapter I of 10 CFR meets the eligibility criteria for categorical exclusion provided that: (1) There is no significant hazards consideration; (2) there is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite; (3) there is no significant increase in individual or cumulative public or occupational radiation exposure; (4) there is no significant construction impact; (5) there is no significant increase in the potential for or consequences from radiological accidents; and (6) the requirements from which an exemption is sought are among those identified in 10 CFR 51.22(c)(25)(vi), including requirements of an administrative, managerial, or organizational nature.

There Is No Significant Hazards Consideration

The criteria for determining whether an action involves a significant hazards consideration are found in 10 CFR 50.92. The proposed exemptions involve only a schedule change regarding the submission of an update to the QATR. The proposed exemptions do not adversely affect plant equipment, operation, or procedures. Therefore, there are no significant hazard considerations, because granting the exemptions would not: (1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

There Is No Significant Change in the Types or Significant Increase in the Amounts of Any Effluents That May Be Released Offsite

The proposed action involves only a schedule change, which is administrative in nature, and does not involve any changes in the types or significant increase in the amounts of any effluents that may be released offsite.

There Is No Significant Increase in Individual or Cumulative Public or Occupational Radiation Exposure

Since the proposed action involves only a schedule change, which is administrative in nature, it does not contribute to any significant increase in occupational or public radiation exposure.

There Is No Significant Construction Impact

Since the proposed action involves only a schedule change, which is administrative in nature, it does not involve any construction impact.

There Is No Significant Increase In the Potential For or Consequences From Radiological Accidents

The proposed action involves only a schedule change, which is administrative in nature and does not impact the potential for or consequences from accidents.

The Requirements From Which the Exemption Is Sought Involve Requirements That are Administrative in Nature

The proposed action involves scheduling requirements and other requirements of an administrative, managerial, or organizational nature, because it is associated with the schedule submittal requirements contained in 10 CFR 50.54(a)(3), and 10 CFR 50.71(e)(4), which require that the QATR be filed annually or six months after each refueling outage, provided the interval between successive updates does not exceed 24 months.

Based on the above, NRC finds that the exemptions meet the eligibility criteria for the categorical exclusion set forth in 10 CFR 51.22(c)(25). Therefore, in accordance with 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared in connection with this exemption request.

IV. Conclusions

Accordingly, the Commission has determined that pursuant to 10 CFR part 50.12, the exemptions are authorized by law, will not present an undue risk to the public health and safety, and are consistent with the common defense and security. Also, special circumstances are present. Therefore, the Commission hereby grants the licensee exemptions from the requirements of 10 CFR 50.54(a)(3) and 10 CFR 50.71(e)(4) for the Farley, Hatch, and Vogtle plants.

The exemptions are effective upon issuance.

Dated at Rockville, Maryland, this 11th day of March 2020.

For the Nuclear Regulatory Commission.

/RA/

Craig G. Erlanger, *Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.*

[FR Doc. 2020–05646 Filed 3–17–20; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2020–99 and CP2020–104; MC2020–100 and CP2020–105; and MC2020–101 and CP2020–106]

New Postal Product

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:* March 20, 2020.

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:

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I. Introduction
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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 3007.301.[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 3010, and 39 CFR part 3020, 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 3015, and 39 CFR part 3020, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2020–99 and CP2020–104; *Filing Title:* USPS Request to Add Priority Mail Contract 596 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* March 12, 2020; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3020.30 *et seq.,* and 39 CFR 3015.5; *Public Representative:* Kenneth R. Moeller; *Comments Due:* March 20, 2020.

2. *Docket No(s).:* MC2020–100 and CP2020–105; *Filing Title:* USPS Request to Add Priority Mail & First-Class Package Service Contract 142 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* March 12, 2020; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3020.30 *et seq.,* and 39 CFR 3015.5; *Public Representative:* Kenneth R. Moeller; *Comments Due:* March 20, 2020.

3. *Docket No(s).:* MC2020–101 and CP2020–106; *Filing Title:* USPS Request to Add Priority Mail & First-Class Package Service Contract 143 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* March 12, 2020; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3020.30 *et seq.,* and 39 CFR 3015.5; *Public Representative:* Kenneth R. Moeller; *Comments Due:* March 20, 2020.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2020–05650 Filed 3–17–20; 8:45 am]

BILLING CODE 7710–FW–P

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

POSTAL SERVICE

Product Change—Priority Mail and First-Class Package Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* March 18, 2020.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on March 12, 2020, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & First-Class Package Service Contract 143 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2020–101, CP2020–106.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2020–05550 Filed 3–17–20; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and First-Class Package Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* March 18, 2020.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service ® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on March 12, 2020, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & First-Class Package Service Contract 142 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2020–100, CP2020–105.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2020–05549 Filed 3–17–20; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service ™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* March 18, 2020.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on March 12, 2020, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Contract 596 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2020–99, CP2020–104.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2020–05548 Filed 3–17–20; 8:45 am]

BILLING CODE 7710–12–P

RAILROAD RETIREMENT BOARD

Sunshine Act Meetings

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: FR Doc. 2020–04861 Filed 3–5–20; 4:15 p.m.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: 10:00 a.m., March 18, 2020.

CHANGES IN THE MEETING: This meeting has been cancelled.

CONTACT PERSON FOR MORE INFORMATION: Stephanie Hillyard, Secretary to the Board, Phone No. 312–751–4920.

Dated: March 13, 2020.

Stephanie Hillyard,

Secretary to the Board.

[FR Doc. 2020–05702 Filed 3–16–20; 11:15 am]

BILLING CODE 7905–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–88368; File No. SR–NYSENAT–2020–09]

Self-Regulatory Organizations; NYSE National, Inc.; Notice of Filing of Proposed Rule Change Amending Rule 7.31 (Orders and Modifiers) Relating to How Orders Are Repriced and Make Related Changes to Rules 7.36 and 7.38

March 12, 2020.

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 February 28, 2020, NYSE National, Inc. (''NYSE National'' or the ''Exchange'') 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 the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 7.31 (Orders and Modifiers) relating to how orders are repriced and make related changes to Rules 7.36 and 7.38. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 7.31 (Orders and Modifiers) relating to how orders are repriced and make related changes to Rules 7.36 and 7.38.

Background

Currently, if an Away Market updates its PBBO and crosses not only the Exchange's BBO, but also displayed orders in the Exchange Book not represented in the BBO, *i.e.,* depth-of-book orders, and then the Exchange's BBO cancels or trades, the Exchange will not disseminate its next-best priced displayed order as its new BBO to the securities information processor (''SIP'').[4] Instead, the Exchange reprices such order before it is disseminated to the SIP.[5]

For example, if the Exchange's BB is $10.05 and on the Exchange Book, there is an order to buy 100 shares ranked Priority 2—Display Orders at $10.04 (''Order A''), Order A is displayed in the Exchange's proprietary depth-of-book

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] The term ''Away Market'' is defined in Rule 1.1(b) to mean ''any exchange, alternative trading system (''ATS'') or other broker-dealer (1) with which the Exchange maintains an electronic linkage and (2) that provides instantaneous responses to orders routed from the Exchange.'' The term ''BBO'' is defined in Rule 1.1(c) to mean the best bid or offer on the Exchange, and the term ''BB'' means the best bid on the Exchange, and the term ''BO'' means the best offer on the Exchange. The term ''PBB'' is defined in Rule 1.1(t) to mean the highest Protected Bid, the term ''PBO'' means the lowest Protected Offer, and ''PBBO'' means the Best Protected Bid and Best Protected Offer. The terms ''Protected Bid'' and ''Protected Offer'' are defined in Rule 1.1(aa). The term ''Exchange Book'' is defined in Rule 1.1(l) to mean the Exchange's electronic file of orders, which contains all orders entered on the Exchange.

[5] *See* Rule 7.31(a)(2)(C), which provides that ''[i]f a BB (BO) that is locked or crossed by an Away Market PBO (PBB) is cancelled, executed or routed and the next best-priced resting Limit Order(s) on the Exchange Book that would become the new BB (BO) would have a display price that would lock or cross the PBO (PBB), such Limit Order(s) to buy (sell) will be assigned a display price one MPV below (above) the PBO (PBB) and a working price equal to the PBO (PBB). When the PBO (PBB) is updated, the Limit Order(s) to buy (sell) will be repriced consistent with the original terms of the order. If a Day ISO to buy (sell) arrives before the PBO (PBB) is updated, such repriced Limit Order(s) to buy (sell) will be repriced to the lower (higher) of the display price of the Day ISO or the original price of the Limit Order(s).''

market data at that $10.04 price but is not disseminated to the SIP.[6] If next, an Away Market publishes a PBO of $10.03, the Exchange's BB of $10.05 will stand its ground. However, if that $10.05 BB trades, cancels, or routes, the Exchange will not disseminate Order A to the SIP as the new BB at $10.04. Instead, as provided for in Rule 7.31(a)(2)(C), Order A will be assigned a display price of $10.02 and a working price of $10.03, which is equal to the Away Market PBO, and will be disseminated to the SIP as the Exchange's BB at $10.02. Order A will be repriced to $10.04 once the Away Market PBBO no longer locks or crosses the Exchange BBO. Each time Order A is repriced, including back to its original price, it is assigned a new working time.[7] The Exchange also applies this repricing functionality to Primary Pegged Orders.[8]

The Exchange believes that no other exchange reprices resting depth orders in this manner. The Exchange understands that in the same scenario on other exchanges, ''Order A'' would stand its ground and be disseminated to the SIP as their new BBO at $10.04, even if that price would cross the Away Market PBO of $10.03. The rules of other exchanges vary regarding how much detail is used to describe circumstances when displayed orders stand their ground, and none explicitly address the specific scenario described above, *i.e.,* when a resting, displayed, depth-of-book order is crossed by an Away Market quotation and then becomes the best-priced order on that exchange. For example:

- The Nasdaq Stock Market LLC (''Nasdaq'') Rule 4756(c)(2) provides that Nasdaq transmits for display to the appropriate network processor its best-priced orders. That Rule specifies exceptions of which orders are not transmitted to the SIP, *i.e.,* the reserve size of orders, the discretionary portion of Discretionary Orders, and Non-Displayed Orders. This rule is silent as to whether resting, displayed, depth-of-book orders that have been locked or crossed by another market center and then become the best-ranked orders on Nasdaq are transmitted to the SIP at their original price. Separately, Nasdaq rules provide that certain previously-displayed orders stand their ground. For example, pursuant to Nasdaq Rules 4702(b)(1)(B) and 4702(b)(2)(B), resting ''Price to Comply Orders'' and ''Price to Display Orders'' entered via RASH, QIX, or FIX will stand their ground if locked or crossed by another market center. But these rules discuss top-of-book displayed orders that are crossed, not depth-of-book orders.
- CBOE BZX Exchange, Inc. (''BZX'') Rule 11.12(b) (Priority of Orders) provides that the best-ranked order(s) to buy and the best-ranked order(s) to sell that are displayable in the BZX Book and the aggregated displayed size of such orders associated with such prices shall be collected and made available to quotation vendors for dissemination pursuant to the requirements of Rule 602 of Regulation NMS. This rule is silent as to whether resting, displayed, depth-of-book orders that have been locked or crossed by another market center and then become the best-ranked orders on BZX are transmitted to the SIP at their original price. BZX Rule 11.13(a)(2)(C) (Order Execution and Routing) discusses how orders execute on BZX when the PBBO is crossed, and how that exchange processes incoming orders during a crossed market. But that rule does not address the scenario described above regarding *resting,* displayed, depth-of-book orders and whether they would be made available to quotation vendors for dissemination at their original price, even when the PBBO is crossed. Under Rule 11.13(b)(4), BZX further provides for optional ''Re-Route Instructions'' pursuant to which if a routable order has been locked or crossed by another market, the routable order on the BZX book would be routed to that other market. However, these are optional instructions, which implies that in the absence of one of these instructions, if a routable order on BZX is locked or crossed by another market, such order stands its ground.
- Investors Exchange LLC (''IEX'') Rule 11.240(c)(1) provides that IEX disseminates the aggregate of its best-ranked displayable orders to quotation vendors for dissemination to the SIPs. IEX Rules 11.190(h)(3)(A)(i) and (h)(3)(B)(i) further provide that resting orders that are displayed at a price that later becomes locked or crossed, and were originally displayed in compliance with rules and regulations of IEX, will maintain their displayed price and quantity.[9] While these rules do not distinguish between displayed orders at the top of the IEX book and depth-of-book displayed orders, these rules appear consistent with the Exchange's proposed change to provide that resting, displayed, depth-of-book orders would stand their ground and are eligible to be disseminated to the SIP as the BBO at their original displayed price.
- Long-Term Stock Exchange (''LTSE'') Rule 11.240(c)(1) provides that LTSE disseminates the aggregate of its best-ranked displayable orders to quotation vendors for dissemination to the SIPs.[10] LTSE Rules 11.190(g)(3)(A)(i) and (g)(3)(B)(i) further provide that resting orders that are displayed at a price that later becomes locked or crossed, and were originally displayed in compliance with rules and regulations of LTSE, will maintain their displayed price and quantity.[11] While these rules do not distinguish between displayed orders at the top of the LTSE book and at depth, these rules appear consistent with the Exchange's proposed change to provide that resting, displayed, depth-of-book orders would stand their ground and are eligible to be disseminated to the SIP as the BBO at their original displayed price.
- MEMX LLC (''MEMX'') has filed a Form 1 application for registration as a national securities exchange pursuant to Section 6 of the Act.[12] Proposed MEMX Rule 11.9(b) provides that the best-ranked order(s) to buy and the best-ranked order(s) to sell that are displayable in the MEMX Book and the aggregate displayed size of such orders associated with such prices shall be collected and made available to the SIP. MEMX claims that its proposed MEMX Rule 11.6(j)(1)(A)(ii), which provides that ''[f]ollowing the initial ranking and display or an order subject to the Display-Price Sliding instruction, an order will only be re-ranked and re-displayed to the extent it achieves a more aggressive price, provided, however, that the Exchange will re-rank an order at the same price as the displayed price in the event such orders' displayed price would be a Locking or Crossing Quotation'' makes clear that an order displayed by MEMX would not be re-priced to a less aggressive price if another market locked or crossed an order displayed by

[6] *See* Rule 7.36(b)(3) (describing which orders are collected and made available to quotation vendors for dissemination pursuant to the requirements of Rule 602 under Regulation NMS under the Act).

[7] *See* Rule 7.36(f)(2) (an order is assigned a new working time any time its working price changes).

[8] *See* Rule 7.31(h)(2)(B).

[9] *See also* Supplementary Material .02 to IEX Rule 11.190(h) (providing that ''[o]rders displayed on the Exchange which were displayed at a price compliant with Regulation NMS are generally permitted to maintain their displayed price in the event an away trading center locks or crosses the price of the IEX displayed order.'')

[10] LTSE has been approved as a registered exchange but is not yet operational.

[11] *See also* Supplementary Material .02 to LTSE Rule 11.190(g).

[12] *See* Securities Exchange Act Release No. 87436 (October 31, 2019), 84 FR 59854 (November 6, 2019) (File No. 1—237). Although MEMX has not yet been approved as an exchange, the Exchange believes that its proposed rules are relevant to this discussion as MEMX expects to be operational in 2020, subject to approval of its Form 1 application.

MEMX.[13] The Exchange understands this response to mean that MEMX would not re-price displayed orders that were at depth that would become the MEMX best bid or offer.

The Exchange proposes to amend its rules to conform how it reprices orders in this scenario to how other exchanges function. The Exchange believes that because such orders did not lock or cross an Away Market PBBO when they were entered on the Exchange and displayed to the Exchange's proprietary market data, such resting orders have priority at the price at which they were originally displayed.[14] In other words, such resting orders did not cause a locked or crossed market condition.

The Exchange further believes that providing priority to such resting orders on the Exchange Book (*e.g.,* disseminating ''Order A'' as a BB at $10.04 in the above-described scenario) would be consistent with Rule 610(d) under the Act (''Rule 610(d)'').[15] Rule 610(d) provides that ''[e]ach national securities exchange . . . shall establish, maintain, and enforce written rules that . . . are reasonably designed to assure the reconciliation of locked quotations in an NMS stock.'' The proposed rule change is consistent with this requirement because in the scenario described above, the Away Market has published a PBO that crosses not only the Exchange's BB, but also other orders that have already been entered on the Exchange and displayed on the Exchange's proprietary market data. Even though such depth-of-book orders have not yet been disseminated to the SIP as part of the Exchange's BBO, those resting orders pre-exist the Away Market quote that crossed them. Therefore, disseminating any pre-existing, displayed orders to the SIP as the new BB at their original price would be consistent with Rule 610(d) because it was the Away Market that crossed previously-displayed orders.

Proposed Rule Change

To effect this proposed rule change, the Exchange proposes to delete Rule 7.31(a)(2)(C) in its entirety. The Exchange also proposes to delete references to this Rule and describe how the Exchange would process orders, as follows.

First, the Exchange proposes several rule changes to specify that previously-displayed orders at any price stand their ground and remain eligible to be quoted or traded at their last-displayed price, even if locked or crossed by an Away Market. The Exchange proposes to specify this principal generally for all displayed orders by amending Rule 7.36(b) to add new subparagraph (4) that would provide that if an Away Market locks or crosses the BBO, the Exchange would not change the display price of any Limit Order ranked Priority 2—Display Orders [16] and any such orders would be eligible to be disseminated as the Exchange's BBO.[17] This proposed rule text both (1) provides specificity that all resting, top-of-book displayed orders stand their ground, which is current functionality,[18] and (2) describes new functionality for previously displayed depth-of-book orders, which would now stand their ground instead of being repriced if they become the Exchange's BBO.

Because such resting orders would no longer be repriced if locked or crossed by an Away Market, such orders would not need to be assigned new working times and would therefore retain priority at their original price. In addition, for market participants that read the Exchange's proprietary market data and are aware of displayed, depth-of-book orders, this proposed change provides greater certainty regarding the price at which a liquidity-taking order would execute on the Exchange.

This proposed rule text therefore promotes transparency and clarity in Exchange rules that all resting, displayed orders, including depth-of-book orders, would stand their ground if locked or crossed by an Away Market. Proposed Rule 7.36(b)(4) is based in part on IEX Rules 11.190(h)(3)(A)(i) and (h)(3)(B)(i) and LTSE Rules 11.190(g)(3)(A)(i) and (g)(3)(B)(i), described above, and is consistent with proposed MEMX Rule 11.6(j)(1)(A)(ii).

The Exchange proposes related changes to remove references to Rule 7.31(a)(2)(C) in connection Primary Pegged Orders and replace that rule text with proposed new functionality that such orders would stand their ground at their last-displayed price. As described above, if the PBBO becomes locked or crossed, displayed orders on the Exchange would stand their ground. The Exchange proposes that in such scenario, resting Primary Pegged Orders, which are dynamically pegged to the PBBO, would similarly stand their ground. As further proposed, if the PBBO becomes locked or crossed, resting Primary Pegged Orders would wait for a PBBO that is not locked or crossed before the display and working price of such orders is adjusted. While the market is locked or crossed, such orders would remain eligible to trade at their current working price.

To effect these changes, the Exchange proposes to amend Rule 7.31(h)(2)(B) relating to Primary Pegged Orders by deleting the last clause of that Rule [19] and amend the last sentence of that paragraph as follows (new text underlined, proposed text for deletion in brackets): ''If after arrival, the PBBO becomes locked or crossed, the Primary Pegged Order will wait for a PBBO that is not locked or crossed before the *display and* working price [is]*are* adjusted[, but]*and* remains eligible to trade at its current working price.''

Second, the Exchange proposes to specify how the Exchange would process orders following a UTP Regulatory Halt in a UTP Security.[20] Because continuous trading did not precede the resumption of trading of such security on the Exchange, the Exchange does not have a displayed quote eligible to stand its ground. Accordingly, to prevent publishing a quote that would lock or cross an Away Market, the Exchange proposes that

[13] *See* Letter from Anders Franzon, General Counsel, MEMX, to Ms. Vanessa Countryman, Secretary, Securities and Exchange Commission, dated February 11, 2020, available here: *https://www.sec.gov/comments/10-237/10237-6795399-208386.pdf.*

[14] If the PBBO is locked or crossed at the time of an order's arrival, such arriving orders would be either routed, cancelled, or repriced, as provided for in Rule 7.37(c) (for routable orders) or Rule 7.31(e) (for non-routable orders). This proposed rule change is applicable only to resting orders.

[15] 17 CFR 242.610(d).

[16] As set forth in Rule 7.36(c), all non-marketable orders are ranked and maintained in the Exchange Book in the following manner: (1) Price; (2) priority category; (3) time; and (4) ranking restrictions applicable to an order or modifier condition. Under Rule 7.36(e)(2), ''Priority 2—Display Orders'' are non-marketable Limit Orders with a displayed working price. Limit Orders that are ranked Priority 2—Display Orders can be top of book or at depth.

[17] As set forth in Rule 7.36(b)(1), the Exchange considers an order to be ''displayed'' when it has been disseminated via a market data feed. Because all orders ranked Priority 2—Display Orders, regardless of price, are displayed via proprietary data feeds, such orders are all ''displayed'' for purposes of Exchange rules.

[18] Current Rule 7.31(e)(1)(A)(iii) specifies that Non-Routable Limit Orders stand their ground when crossed by an Away Market PBBO.

[19] The last clause of current Rule 7.31(h)(2)(B) provides: ''provided that, if a resting Limit Order on the Exchange Book is assigned a new display price and working price pursuant to Rule 7.31(a)(2)(C) and the PBBO is still locked or crossed, a resting Primary Pegged Order will also be assigned a new display price and working price pursuant to Rule 7.31(a)(2)(C).''

[20] The term ''UTP Security'' is defined in Rule 1.1(ii) to mean a security that is listed on a national securities exchange other than the Exchange and that trades on the Exchange pursuant to unlisted trading privileges and the term ''UTP Regulatory Halt'' is defined in Rule 1.1(kk) to mean a trade suspension, halt, or pause caused by the UTP Listing Market in a UTP Security that requires all market centers to halt trading in that security. The term ''UTP Listing Market'' is defined in Rule 1.1(jj) to mean the primary listing market for a UTP Security.

before the Exchange publishes a quote, orders that are marketable against a protected quotation on an Away Market would be either routed (if routable) or cancelled (if non-routable).

The second clause of proposed new Rule 7.36(b)(4) would address how the Exchange would process orders before resuming trading and publishing a quote in a UTP Security following a UTP Regulatory Halt. This proposed rule text would be an exception to the first half of the rule text, described above, that previously-displayed orders stand their ground. The Exchange proposes this exception because during a UTP Regulatory Halt, there is no continuous trading and the Exchange ''zeroes'' out its quote, meaning the Exchange removes its BBO from the SIP. However, during a UTP Regulatory Halt, the Exchange may still have orders on its book. Specifically, as set forth in Rule 7.18(b), during a UTP Regulatory Halt, the Exchange cancels resting non-displayed orders and maintains all other resting orders in the Exchange Book at their last working price and display price. The Exchange does not accept new orders during such a halt. As provided for in Rule 7.18(a), the Exchange does not resume trading, including publishing a quote, in such security until it receives notification from the UTP Listing Market that the halt or suspension is no longer in effect and it has received the first Price Band in that security. The Exchange proposes that once it is eligible to resume trading, previously-displayed Limit Orders, *i.e.,* the orders entered before the UTP Regulatory Halt, would be routed (if routable) or cancelled (if non-routable) if such orders would be marketable against protected quotations on Away Markets.

For example, if before a UTP Regulatory Halt in XYZ security, the Exchange's BBO was $10.10 (100 shares) × $10.12 (100 shares), and before the Exchange resumes trading following that UTP Regulatory Halt, the first PBBO is $10.08 (100 shares) × $10.09 (100 shares), because the Exchange's former best bid of $10.10 is marketable against the new $10.09 PBO, the Exchange would either route that order (if routable) or cancel it (if non-routable). The Exchange would publish the former $10.12 because it is not marketable against an Away Market quotation.

The Exchange believes that following a UTP Regulatory Halt, orders that would lock or cross the Away Market PBBO should either be routed (if routable) or cancelled (if non-routable) if they would be marketable against protected quotations on Away Markets. The Exchange believes that routing or cancelling such orders is consistent with Rule 610(d) because the Away Market does not have an obligation to prevent locking or crossing an Exchange quote in this scenario. Therefore, in this scenario, to prevent locking or crossing the Away Market PBBO, the Exchange would either route or cancel previously-entered orders before publishing a quote.

Third, the Exchange proposes to apply the proposed processing of orders, described above, to odd-lot orders. In other words, odd-lot orders would no longer be processed differently than orders that are a round lot or greater in size. Currently, Rule 7.38(b)(1) and subparagraphs (A)–(C) describe how the working and display price of odd-lot orders are adjusted in relation to the contra-side PBBO. In short, currently, the working and display prices of odd-lot orders are bound by the PBBO, which means that resting odd-lot orders can be repriced if the PBBO changes or becomes locked or crossed.[21]

As proposed, odd-lot sized orders would be priced the same as orders of a round-lot size or higher, and if they are designated Priority 2—Display Orders, they would stand their ground if locked or crossed by an Away Market PBBO. To effect this change, the Exchange proposes to delete Rule 7.38(b)(1) and sub-paragraphs (A)–(C) in their entirety. The Exchange also proposes to delete the clause ''provided that'' at the end of Rule 7.38(b) and make a non-substantive change to that Rule to replace the term ''in'' with the term ''on.'' As a result of these changes, Rule 7.38(b) would provide, without any qualifiers, that ''[r]ound lot, mixed lot and odd-lot orders are treated in the same manner on the Exchange.'' The Exchange proposes an additional non-substantive change to renumber current Rule 7.38(b)(2) as Rule 7.38(c).

Fourth, because displayed odd-lot orders would stand their ground, the Exchange proposes to amend Rule 7.31(d)(1) to add new subparagraph (F) relating to Reserve Orders to specify new functionality of how non-routable Reserve Orders would be replenished if the display quantity of a resting Reserve Order is decremented to an odd-lot size when the PBBO is crossed. The Exchange proposes this change only for non-routable Reserve Orders. These changes are not necessary for a routable Reserve Order because when such order replenishes, the replenish quantity is evaluated for routing to Away Markets and thus would not be displayed at a price that crosses an Away Market.

As proposed in new subparagraph (F) to Rule 7.31(d)(1), if the PBBO is crossed and the display quantity of a Reserve Order to buy (sell) that is a Non-Routable Limit Order is decremented to less than a round lot, the display price and working price of such Reserve Order would be not change. This proposed rule text is consistent with the change, described above, that resting displayed orders, including odd-lot sized orders, would stand their ground if crossed by an Away Market. The proposed rule would further provide that the reserve interest that replenishes the display quantity would be assigned a display price one MPV below (above) the PBO (PBB) and a working price equal to the PBO (PBB). Because this is the first time such interest would be displayed, the Exchange proposes to adjust the display and working price so that the replenished quantity would not lock or cross the Away Market, which is the same manner that an arriving Non-Routable Limit Order is priced.[22]

When the PBBO uncrosses, the display price and working price would be adjusted as provided for under paragraph (e)(1) of this Rule relating to Non-Routable Limit Orders.

Fifth, as described above, displayed orders would stand their ground if locked or crossed by an Away Market. However, non-displayed orders do not. As set forth in Rule 7.31(d)(2)(A), the working price of a resting Non-Displayed Limit Order will be adjusted based on the limit price of the order. If the limit price of a Non-Displayed Limit Order to buy (sell) is at or below (above) the PBO (PBB), it will have a working price equal to the limit price. If the limit price of a Non-Displayed Limit Order to buy (sell) is above (below) the PBO

[21] Current Rule 7.38(b)(1) provides that ''[t]he working and display price of an odd lot order will be adjusted both on arrival and when resting on the Exchange Book as follows: (A) If the limit price of an odd lot order to buy (sell) is at or below (above) the PBO (PBB), it will have a working and display price equal to the limit price. (B) If the limit price of an odd lot order to buy (sell) is above (below) the PBO (PBB), it will have a working price equal to the PBO (PBB). The display price will also be adjusted to the PBO (PBB) unless the order's instruction requires a display price that is different from the PBBO. (C) If the PBBO is locked or crossed and the limit price of an odd lot order to buy (sell) is above (below) the PBO (PBB), it will have a working and display price equal to the PBB (PBO). The working and display price of such odd lot order will not be adjusted again until the PBBO unlocks or uncrosses.''

[22] *See* Rule 7.31(e)(1)(A) (describing how arriving Non-Routable Limit Order is priced). On Nasdaq, a Price to Comply Order with Reserve Size replenishes in a similar manner. *See* Nasdaq Rule 4703(h); *see also* Supplementary Material .02 to IEX Rule 11.190(h) (''When a reserve order refreshes its displayed portion, the refreshing shares are not permitted to be displayed at a price that locks or crosses the price of a protected quotation on an away market and are subject to display-price sliding'').

(PBB), it will have a working price equal to the PBO (PBB). The Exchange also proposes to amend Rule 7.31(d)(1) to provide that the working price of the reserve interest of resting Reserve Orders, which are non-displayed, would be adjusted in the same manner that the working price of Non-Displayed Limit Orders are adjusted.

To effect this change, the Exchange proposes to amend Rule 7.31(d)(1) to add the following sentence: ''The working price of the reserve interest of a resting Reserve Order will be adjusted in the same manner as a Non-Displayed Limit Order, as provided for in paragraph (d)(2)(A) of this Rule.'' The Exchange understands that at least one other exchange also adjusts the price of the non-displayed portion of Reserve Orders in the same manner that such exchange adjusts the price of non-displayed orders.[23]

Together with the proposed rule change described above to Rule 7.36(b), these rule changes make clear that on the Exchange, if crossed by an Away Market PBBO, displayed orders would stand their ground and non-displayed orders, including the reserve interest of resting Reserve Orders, would be repriced based off of the PBBO.

Implementation

Because of the technology changes associated with this proposed rule change, the Exchange will announce the implementation date of this proposed rule change by Trader Update. Subject to effectiveness of this proposed rule change, the Exchange anticipates that the implementation date will be in the Spring of 2020.

2. Statutory Basis

The Exchange believes that the proposal is consistent with Section 6(b) of the Act,[24] in general, and furthers the objectives of Sections 6(b)(5) of the Act,[25] in particular, because it is 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 mechanisms of, a free and open market and a national market system and, in general, to protect investors and the public interest and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that deleting Rule 7.31(a)(2)(C) and the related proposed amendment to Rule 7.36(b) to add new sub-paragraph (4) would remove impediments to and perfect the mechanism of a free and open market and a national market system because they would promote transparency in Exchange rules that previously-displayed orders would stand their ground if locked or crossed by an Away Market PBBO. The proposed rule changes would further promote transparency because they make clear that resting, displayed, depth-of-book orders that have been locked or crossed by an Away Market PBBO would be eligible to be disseminated to the SIP at their original price if they become the BBO.

The Exchange believes that previously-displayed orders, including depth-of-book orders, have priority at such price and should be able to stand their ground if locked or crossed by an Away Market. The Exchange therefore believes it is consistent with this principle to delete Rule 7.31(a)(2)(C) and change functionality on the Exchange for such orders to stand their ground and not be repriced if another market locks or crosses their price. The proposed change therefore benefits those resting orders because they would be able to keep their original working time and any priority ranking associated with such working time. The proposed change would also benefit liquidity takers, who would have greater certainty regarding the price at which they would receive an execution on the Exchange.

Moreover, the proposed change is consistent with how other exchanges function. While the rules of other exchanges differ in level of detail, these proposed changes are based in part on IEX Rules 11.190(h)(3)(A)(i) and (h)(3)(B)(i)and LTSE Rules 11.190(g)(3)(A)(i) and (g)(3)(B)(i), which similarly provide that previously-displayed orders on those exchanges maintain their display price and quantity if locked or crossed by an another market center. The proposal is also similar to how MEMX proposes it would function if approved as an exchange.

The Exchange further believes that these proposed amendments are consistent with Rule 610(d). If an Away Market publishes a PBBO that crosses not only the Exchange's BBO, but also resting, displayed, depth-of-book orders, it was the Away Market that crossed previously-displayed orders. If such previously-displayed, depth-of-book orders become the Exchange's BBO, the Exchange believes it is appropriate to disseminate those previously-displayed prices and quantities to the SIP as the new BBO because those resting orders pre-existed the Away Market quote that locked or crossed them.

For the same reasons, the Exchange believes that the proposed changes to Primary Pegged Orders would remove impediments to and perfect the mechanism of a free and open market and a national market system because displayed orders that are pegged to a dynamic price would stand their ground at their original displayed price if locked or crossed by an Away Market, which is consistent with the proposed rule change that all displayed orders would stand their ground. These proposed rule changes also promote transparency by specifying that such orders would continue to be eligible to trade at their original working price, and that their display and working prices would not be adjusted until the PBBO is no longer locked or crossed.

The Exchange further believes that routing or cancelling orders that are marketable against an Away Market PBBO following a UTP Regulatory Halt would also remove impediments to and perfect the mechanism of a free and open market and a national market system because in this scenario, the Away Market would not have had an obligation to prevent displaying a locking or crossing quotation. The Exchange proposes to avoid locking or crossing an Away Market PBBO in this scenario by routing or cancelling previously-displayed orders, as applicable. These proposed changes would reduce the number of times resting orders would be repriced, thereby increasing determinism for the price at which orders would be executed on the Exchange.

The Exchange believes that processing odd-lot sized orders in the same manner as round-lot sized orders would remove impediments to and perfect the mechanism of a free and open market because the same principle applies: an order of any size that has been displayed has priority at that price if an Away Market subsequently locks or crosses that price. In addition, the Exchange believes that processing odd-lot orders the same as round-lot sized orders is not novel as it is consistent with the rules of other exchanges.[26]

[23] *See* IEX Rule 11.190(b)(2) (stating that the non-displayed portion of reserve orders are treated as non-displayed orders). IEX reprices its non-displayed orders differently from how the Exchange reprices Non-Displayed Limit Orders. *See* IEX Rule 11.190(h)(3)(D). Importantly, both IEX and the Exchange reprice non-displayed orders when crossed by an Away Market PBBO.

[24] 15 U.S.C. 78f(b).

[25] 15 U.S.C. 78f(b)(5).

[26] *See, e.g.,* Nasdaq Rules 4703(b)(3) (defining the term ''odd lot'' as an order attribute) and 4702 (describing which order attributes are available for

Finally, the Exchange believes that the proposed changes to Reserve Orders would remove impediments to and perfect the mechanism of a free and open market because it would apply these principles to a Non-Routable Limit Order that is also a Reserve Order. This proposed functionality is also consistent with how Nasdaq and IEX process non-routable orders with reserve interest.[27] The proposed change to reprice the reserve interest of resting Reserve Orders in the same manner as a Non-Displayed Limit Order is priced would also remove impediments to and perfect the mechanism of a free and open market because it would promote consistency in Exchange rules regarding how similar orders are priced when crossed by an Away Market. The proposed change is also consistent with how IEX processes the reserve interest of Reserve Orders.[28]

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[29] the Exchange believes that the proposed rule change would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed change is competitive because it is designed to conform how the Exchange processes previously-displayed orders with the functionality available on other exchanges, *i.e.,* that such orders would stand their ground if locked or crossed by an Away Market and be eligible to be disseminated to the SIP at their original price. The Exchange believes that the proposed change would promote competition because fewer orders would need to be repriced on the Exchange and therefore liquidity providers seeking for their orders to retain priority may route additional orders to the Exchange. Likewise, liquidity takers may be more likely to route orders to the Exchange if they have greater determinism regarding the price at which their orders would be executed.

Without this proposed rule change regarding how displayed orders would stand their ground if locked or crossed by an Away Market, the Exchange is currently at a competitive disadvantage vis-à-vis all other equity exchanges, which do not reprice orders in this manner. As discussed above, displayed orders on all other equity exchanges, including the two exchanges that recently had their Form 1 applications to be approved as an exchange (IEX and LTSE), stand their ground when locked or crossed by an Away Market and such orders are disseminated to the SIP if they become those exchanges' best bid or offer. In addition, MEMX proposes that displayed orders would stand their ground if locked or crossed by an Away Market.

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–NYSENAT–2020–09 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–NYSENAT–2020–09. 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 offices 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–NYSNAT–2020–09, and should be submitted on or before April 8, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[30]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–05556 Filed 3–17–20; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–88369; File No. SR–NYSEArca-2020–17]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of Proposed Rule Change Amending Rule 7.31–E (Orders and Modifiers) Relating to How Orders Are Repriced and Make Related Changes to Rules 7.35–E, 7.36–E, and 7.38–E

March 12, 2020.

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 February 28, 2020, NYSE Arca, Inc. (''NYSE Arca'' or the ''Exchange'') filed with the

orders on Nasdaq, without any discussion of odd-lot sized orders being priced differently than round-lot sized orders). *See also* BZX Rules 11.10 (defining the term ''odd lot'') and 11.9 (describing BZX Orders and Modifiers, without any discussion of odd-lot sized orders being priced differently than round-lot sized orders).

[27] *See supra* note 22.

[28] *See supra* note 23.

[29] 15 U.S.C. 78f(b)(8).

[30] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

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 the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 7.31–E (Orders and Modifiers) relating to how orders are repriced and make related changes to Rules 7.35–E, 7.36–E, and 7.38–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 Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 7.31–E (Orders and Modifiers) relating to how orders are repriced and make related changes to Rules 7.35–E, 7.36–E, and 7.38–E.

Background

Currently, if an Away Market updates its PBBO and crosses not only the Exchange's BBO, but also displayed orders in the Exchange Book not represented in the BBO, *i.e.,* depth-of-book orders, and then the Exchange's BBO cancels or trades, the Exchange will not disseminate its next-best priced displayed order as its new BBO to the securities information processor (''SIP'').[4] Instead, the Exchange reprices such order before it is disseminated to the SIP.[5]

For example, if the Exchange's BB is $10.05 and on the Exchange Book, there is an order to buy 100 shares ranked Priority 2—Display Orders at $10.04 (''Order A''), Order A is displayed in the Exchange's proprietary depth-of-book market data at that $10.04 price but is not disseminated to the SIP.[6] If next, an Away Market publishes a PBO of $10.03, the Exchange's BB of $10.05 will stand its ground. However, if that $10.05 BB trades, cancels, or routes, the Exchange will not disseminate Order A to the SIP as the new BB at $10.04. Instead, as provided for in Rule 7.31–E(a)(2)(C), Order A will be assigned a display price of $10.02 and a working price of $10.03, which is equal to the Away Market PBO, and will be disseminated to the SIP as the Exchange's BB at $10.02. Order A will be repriced to $10.04 once the Away Market PBBO no longer locks or crosses the Exchange BBO. Each time Order A is repriced, including back to its original price, it is assigned a new working time.[7] The Exchange also applies this repricing functionality to Primary Pegged Orders and following an auction.[8]

The Exchange believes that no other exchange reprices resting depth orders in this manner. The Exchange understands that in the same scenario on other exchanges, ''Order A'' would stand its ground and be disseminated to the SIP as their new BBO at $10.04, even if that price would cross the Away Market PBO of $10.03. The rules of other exchanges vary regarding how much detail is used to describe circumstances when displayed orders stand their ground, and none explicitly address the specific scenario described above, *i.e.,* when a resting, displayed, depth-of-book order is crossed by an Away Market quotation and then becomes the best-priced order on that exchange. For example:

- The Nasdaq Stock Market LLC (''Nasdaq'') Rule 4756(c)(2) provides that Nasdaq transmits for display to the appropriate network processor its best-priced orders. That Rule specifies exceptions of which orders are not transmitted to the SIP, *i.e.,* the reserve size of orders, the discretionary portion of Discretionary Orders, and Non-Displayed Orders. This rule is silent as to whether resting, displayed, depth-of-book orders that have been locked or crossed by another market center and then become the best-ranked orders on Nasdaq are transmitted to the SIP at their original price. Separately, Nasdaq rules provide that certain previously-displayed orders stand their ground. For example, pursuant to Nasdaq Rules 4702(b)(1)(B) and 4702(b)(2)(B), resting ''Price to Comply Orders'' and ''Price to Display Orders'' entered via RASH, QIX, or FIX will stand their ground if locked or crossed by another market center. But these rules discuss top-of-book displayed orders that are crossed, not depth-of-book orders.
- CBOE BZX Exchange, Inc. (''BZX'') Rule 11.12(b) (Priority of Orders) provides that the best-ranked order(s) to buy and the best-ranked order(s) to sell that are displayable in the BZX Book and the aggregated displayed size of such orders associated with such prices shall be collected and made available to quotation vendors for dissemination pursuant to the requirements of Rule 602 of Regulation NMS. This rule is silent as to whether resting, displayed, depth-of-book orders that have been locked or crossed by another market center and then become the best-ranked orders on BZX are transmitted to the SIP at their original price. BZX Rule 11.13(a)(2)(C) (Order Execution and Routing) discusses how orders execute on BZX when the PBBO is crossed, and how that exchange processes incoming orders during a crossed market. But that rule does not address the scenario described above regarding *resting,* displayed, depth-of-book orders and whether they would be made available to quotation vendors for dissemination at their original price, even when the

[4] The term ''Away Market'' is defined in Rule 1.1 to mean ''any exchange, alternative trading system (''ATS'') or other broker-dealer (1) with which the Exchange maintains an electronic linkage and (2) that provides instantaneous responses to orders routed from the Exchange.'' The term ''BBO'' is defined in Rule 1.1 to mean the best bid or offer on the Exchange, and the term ''BB'' means the best bid on the Exchange, and the term ''BO'' means the best offer on the Exchange. The term ''PBB'' is defined in Rule 1.1 to mean the highest Protected Bid, the term ''PBO'' means the lowest Protected Offer, and ''PBBO'' means the Best Protected Bid and Best Protected Offer. The terms ''Protected Bid'' and ''Protected Offer'' are defined in Rule 1.1. The term ''Exchange Book'' is defined in Rule 1.1 to mean the Exchange's electronic file of orders, which contains all orders entered on the Exchange.

[5] *See* Rule 7.31–E(a)(2)(C), which provides that ''[i]If a BB (BO) that is locked or crossed by an Away Market PBO (PBB) is cancelled, executed or routed and the next best-priced resting Limit Order(s) on the Exchange Book that would become the new BB (BO) would have a display price that would lock or cross the PBO (PBB), such Limit Order(s) to buy (sell) will be assigned a display price one MPV below (above) the PBO (PBB) and a working price equal to the PBO (PBB). When the PBO (PBB) is updated, the Limit Order(s) to buy (sell) will be repriced consistent with the original terms of the order. If a Day ISO to buy (sell) arrives before the PBO (PBB) is updated, such repriced Limit Order(s) to buy (sell) will be repriced to the lower (higher) of the display price of the Day ISO or the original price of the Limit Order(s).''

[6] *See* Rule 7.36–E(b)(3) (describing which orders are collected and made available to quotation vendors for dissemination pursuant to the requirements of Rule 602 under Regulation NMS under the Act).

[7] *See* Rule 7.36–E(f)(2) (an order is assigned a new working time any time its working price changes).

[8] *See* Rules 7.31–E(h)(2)(B) and 7.35–E(h)(3)(A).

PBBO is crossed. Under Rule 11.13(b)(4), BZX further provides for optional ''Re-Route Instructions'' pursuant to which if a routable order has been locked or crossed by another market, the routable order on the BZX book would be routed to that other market. However, these are optional instructions, which implies that in the absence of one of these instructions, if a routable order on BZX is locked or crossed by another market, such order stands its ground.

• Investors Exchange LLC (''IEX'') Rule 11.240(c)(1) provides that IEX disseminates the aggregate of its best-ranked displayable orders to quotation vendors for dissemination to the SIPs. IEX Rules 11.190(h)(3)(A)(i) and (h)(3)(B)(i) further provide that resting orders that are displayed at a price that later becomes locked or crossed, and were originally displayed in compliance with rules and regulations of IEX, will maintain their displayed price and quantity.[9] While these rules do not distinguish between displayed orders at the top of the IEX book and depth-of-book displayed orders, these rules appear consistent with the Exchange's proposed change to provide that resting, displayed, depth-of-book orders would stand their ground and are eligible to be disseminated to the SIP as the BBO at their original displayed price.

• Long-Term Stock Exchange (''LTSE'') Rule 11.240(c)(1) provides that LTSE disseminates the aggregate of its best-ranked displayable orders to quotation vendors for dissemination to the SIPs.[10] LTSE Rules 11.190(g)(3)(A)(i) and (g)(3)(B)(i) further provide that resting orders that are displayed at a price that later becomes locked or crossed, and were originally displayed in compliance with rules and regulations of LTSE, will maintain their displayed price and quantity.[11] While these rules do not distinguish between displayed orders at the top of the LTSE book and at depth, these rules appear consistent with the Exchange's proposed change to provide that resting, displayed, depth-of-book orders would stand their ground and are eligible to be disseminated to the SIP as the BBO at their original displayed price.

• MEMX LLC (''MEMX'') has filed a Form 1 application for registration as a national securities exchange pursuant to Section 6 of the Act.[12] Proposed MEMX Rule 11.9(b) provides that the best-ranked order(s) to buy and the best-ranked order(s) to sell that are displayable in the MEMX Book and the aggregate displayed size of such orders associated with such prices shall be collected and made available to the SIP. MEMX claims that its proposed MEMX Rule 11.6(j)(1)(A)(ii), which provides that ''[f]ollowing the initial ranking and display or an order subject to the Display-Price Sliding instruction, an order will only be re-ranked and re-displayed to the extent it achieves a more aggressive price, provided, however, that the Exchange will re-rank an order at the same price as the displayed price in the event such orders' displayed price would be a Locking or Crossing Quotation'' makes clear that an order displayed by MEMX would not be re-priced to a less aggressive price if another market locked or crossed an order displayed by MEMX.[13] The Exchange understands this response to mean that MEMX would not re-price displayed orders that were at depth that would become the MEMX best bid or offer.

The Exchange proposes to amend its rules to conform how it reprices orders in this scenario to how other exchanges function. The Exchange believes that because such orders did not lock or cross an Away Market PBBO when they were entered on the Exchange and displayed to the Exchange's proprietary market data, such resting orders have priority at the price at which they were originally displayed.[14] In other words, such resting orders did not cause a locked or crossed market condition.

The Exchange further believes that providing priority to such resting orders on the Exchange Book (*e.g.,* disseminating ''Order A'' as a BB at $10.04 in the above-described scenario) would be consistent with Rule 610(d) under the Act (''Rule 610(d)'').[15] Rule 610(d) provides that ''[e]ach national securities exchange . . . shall establish, maintain, and enforce written rules that . . . are reasonably designed to assure the reconciliation of locked quotations in an NMS stock.'' The proposed rule change is consistent with this requirement because in the scenario described above, the Away Market has published a PBO that crosses not only the Exchange's BB, but also other orders that have already been entered on the Exchange and displayed on the Exchange's proprietary market data. Even though such depth-of-book orders have not yet been disseminated to the SIP as part of the Exchange's BBO, those resting orders pre-exist the Away Market quote that crossed them. Therefore, disseminating any pre-existing, displayed orders to the SIP as the new BB at their original price would be consistent with Rule 610(d) because it was the Away Market that crossed previously-displayed orders.

Proposed Rule Change

To effect this proposed rule change, the Exchange proposes to delete Rule 7.31–E(a)(2)(C) in its entirety. The Exchange also proposes to delete references to this Rule and describe how the Exchange would process orders, as follows.

First, the Exchange proposes rule changes to specify that previously-displayed orders at any price stand their ground and remain eligible to be quoted or traded at their last-displayed price, even if locked or crossed by an Away Market. The Exchange proposes to specify this principal generally for all displayed orders by amending Rule 7.36–E(b) to add new subparagraph (4) that would provide that if an Away Market locks or crosses the BBO, the Exchange would not change the display price of any Limit Order ranked Priority 2—Display Orders[16] and any such orders would be eligible to be disseminated as the Exchange's BBO.[17] This proposed rule text both (1) provides specificity that all resting, top-of-book displayed orders stand their

[9] *See also* Supplementary Material .02 to Rule 11.190(h) (providing that ''[o]rders displayed on the Exchange which were displayed at a price compliant with Regulation NMS are generally permitted to maintain their displayed price in the event an away trading center locks or crosses the price of the IEX displayed order.'')

[10] LTSE has been approved as a registered exchange but is not yet operational.

[11] *See also* Supplementary Material .02 to LTSE Rule 11.190(g).

[12] *See* Securities Exchange Act Release No. 87436 (October 31, 2019), 84 FR 59854 (November 6, 2019) (File No. 1—237). Although MEMX has not yet been approved as an exchange, the Exchange believes that its proposed rules are relevant to this discussion as MEMX expects to be operational in 2020, subject to approval of its Form 1 application.

[13] *See* Letter from Anders Franzon, General Counsel, MEMX, to Ms. Vanessa Countryman, Secretary, Securities and Exchange Commission, dated February 11, 2020, available here: *https://www.sec.gov/comments/10-237/10237-6795399-208386.pdf.*

[14] If the PBBO is locked or crossed at the time of an order's arrival, such arriving orders would be either routed, cancelled, or repriced, as provided for in Rule 7.37–E(c) (for routable orders) or Rule 7.31–E(e) (for non-routable orders). This proposed rule change is applicable only to resting orders.

[15] 17 CFR 242.610(d).

[16] As set forth in Rule 7.36–E(c), all non-marketable orders are ranked and maintained in the Exchange Book in the following manner: (1) price; (2) priority category; (3) time; and (4) ranking restrictions applicable to an order or modifier condition. Under Rule 7.36–E(e)(2), ''Priority 2—Display Orders'' are non-marketable Limit Orders with a displayed working price. Limit Orders that are ranked Priority 2—Display Orders can be top of book or at depth.

[17] As set forth in Rule 7.36–E(b)(1), the Exchange considers an order to be ''displayed'' when it has been disseminated via a market data feed. Because all orders ranked Priority 2—Display Orders, regardless of price, are displayed via proprietary data feeds, such orders are all ''displayed'' for purposes of Exchange rules.

ground, which is current functionality,[18] and (2) describes new functionality for previously displayed depth-of-book orders, which would now stand their ground instead of being repriced if they become the Exchange's BBO.

Because such resting orders would no longer be repriced if locked or crossed by an Away Market, such orders would not need to be assigned new working times and would therefore retain priority at their original price. In addition, for market participants that read the Exchange's proprietary market data and are aware of displayed, depth-of-book orders, this proposed change provides greater certainty regarding the price at which a liquidity-taking order would execute on the Exchange.

This proposed rule text therefore promotes transparency and clarity in Exchange rules that all resting, displayed orders, including depth-of-book orders, would stand their ground if locked or crossed by an Away Market. Proposed Rule 7.36–E(b)(4) is based in part on IEX Rules 11.190(h)(3)(A)(i) and (h)(3)(B)(i) and LTSE Rules 11.190(g)(3)(A)(i) and (g)(3)(B)(i), described above, and is consistent with proposed MEMX Rule 11.6(j)(1)(A)(ii).

The Exchange proposes related changes to remove references to Rule 7.31–E(a)(2)(C) in connection with Primary Pegged Orders and replace that rule text with proposed new functionality that such orders would stand their ground at their last-displayed price. As described above, if the PBBO becomes locked or crossed, displayed orders on the Exchange would stand their ground. The Exchange proposes that in such scenario, resting Primary Pegged Orders, which are dynamically pegged to the PBBO, would similarly stand their ground. As further proposed, if the PBBO becomes locked or crossed, Primary Pegged Orders would wait for a PBBO that is not locked or crossed before the display and working price of such orders are adjusted. While the market is locked or crossed, such orders would remain eligible to trade at their current working price.

To effect this change, the Exchange proposes to amend Rule 7.31–E(h)(2)(B) relating to Primary Pegged Orders by deleting the last clause of that Rule[19] and amend the last sentence of that paragraph as follows (new text underlined, proposed text for deletion in brackets): ''If after arrival, the PBBO becomes locked or crossed, the Primary Pegged Order will wait for a PBBO that is not locked or crossed before the *display and* working price [is]*are* adjusted[, but]*and* remains eligible to trade at its current working price.''

Second, the Exchange proposes to specify how the Exchange would process orders following either a UTP Regulatory Halt in a UTP Security or an Auction that is not preceded by continuous trading.[20] Because continuous trading did not precede either of these scenarios, the Exchange does not have a displayed quote eligible to stand its ground. Accordingly, to prevent publishing a quote that would lock or cross an Away Market, the Exchange proposes that before the Exchange publishes a quote following either of these scenarios, orders that are marketable against a protected quotation on an Away Market would be either routed (if routable) or cancelled (if non-routable).

The second clause of proposed Rule 7.36–E(b)(4) would address how the Exchange would process orders before resuming trading and publishing a quote in a UTP Security following a UTP Regulatory Halt. This proposed rule text would be an exception to the first half of the rule text, described above, that previously-displayed orders stand their ground. The Exchange proposes this exception because during a UTP Regulatory Halt, there is no continuous trading and the Exchange ''zeroes'' out its quote, meaning the Exchange removes its BBO from the SIP. However, during a UTP Regulatory Halt, the Exchange may still have orders on its book. Specifically, as set forth in Rule 7.18–E(b), during a UTP Regulatory Halt, the Exchange cancels resting non-displayed orders and maintains all other resting orders in the Exchange Book at their last working price and display price. The Exchange does not accept new orders during such a halt. As provided for in Rule 7.18–E(a), the Exchange does not resume trading, including publishing a quote, in such security until it receives notification from the UTP Listing Market that the halt or suspension is no longer in effect and it has received the first Price Band in that security. The Exchange proposes that once it is eligible to resume trading, previously-displayed Limit Orders, *i.e.,* the orders entered before the UTP Regulatory Halt, would be routed (if routable) or cancelled (if non-routable) if such orders would be marketable against protected quotations on Away Markets.

For example, if before a UTP Regulatory Halt in XYZ security, the Exchange's BBO was $10.10 (100 shares) × $10.12 (100 shares), and before the Exchange resumes trading following that UTP Regulatory Halt, the first PBBO is $10.08 (100 shares) × $10.09 (100 shares), because the Exchange's former best bid of $10.10 is marketable against the new $10.09 PBO, the Exchange would either route that order (if routable) or cancel it (if non-routable). The Exchange would publish the former $10.12 because it is not marketable against an Away Market quotation.

To specify how orders would be processed before publishing a quote when transitioning from a prior trading session or following the Core Open or Closing Auction, *i.e.,* transitions preceded by continuous trading and the Exchange has a published quote immediately preceding the transition, the Exchange proposes that those displayed orders are eligible to stand their ground, as described in proposed Rule 7.36–E(b)(4) above. To effect this change, the Exchange proposes to delete the last clause of Rule 7.35–E(h)(3)(A)(i), which provides that if the new published quote is worse than the previously-published quote and would lock or cross the PBBO, the display price of Limit Orders will be adjusted consistent with Rule 7.31–E(a)(2)(C). This proposed change is consistent with the proposed change to Rule 7.36–E(b), described above, that previously-displayed orders stand their ground if crossed by an Away Market. Because this paragraph is about scenarios where an Auction follows continuous trading and there was a previously-published quote, the Exchange also proposes a non-substantive, clarifying amendment to Rule 7.35–E(h)(3)(A)(i) to specify that this subparagraph of the Rule would be applicable to Closing Auctions that are preceded by continuous trading.

To specify how orders would be processed before publishing a quote when transitioning to continuous trading following an Auction that is not preceded by continuous trading, the Exchange proposes to amend Rule 7.35–

[18] Current Rule 7.31–E(e)(1)(A)(iii) specifies that Non-Routable Limit Orders stand their ground when crossed by an Away Market PBBO.

[19] The last clause of current Rule 7.31–E(h)(2)(B) provides: ''provided that, if a resting Limit Order on the Exchange Book is assigned a new display price and working price pursuant to Rule 7.31–E(a)(2)(C) and the PBBO is still locked or crossed, a resting Primary Pegged Order will also be assigned a new display price and working price pursuant to Rule 7.31–E(a)(2)(C).''

[20] The term ''UTP Security'' is defined in Rule 1.1 to mean a security that is listed on a national securities exchange other than the Exchange and that trades on the Exchange pursuant to unlisted trading privileges and the term ''UTP Regulatory Halt'' is defined in Rule 1.1 to mean a trade suspension, halt, or pause caused by the UTP Listing Market in a UTP Security that requires all market centers to halt trading in that security. The term ''UTP Listing Market'' is defined in Rule 1.1 to mean the primary listing market for a UTP Security.

E(h)(3)(A)(ii) regarding how orders would be processed before publishing a quote when transitioning to continuous trading following an Auction that is not preceded by continuous trading. Currently, before publishing following a Trading Halt Auction: (1) Previously-live Limit Orders that are designated with a Proactive if Locked/Crossed Modifier or that would be the result of reserve interest replenishing the display quantity of a routable Reserve Order will route, if marketable against protected quotations on Away Markets; (2) previously-live orders that are marketable against other orders in the NYSE Arca Book and that would not trade-through a protected quotation will trade; and (3) the display price of all other orders that are marketable against a protected quotation on an Away Market will be adjusted consistent with Rule 7.31–E(a)(2)(C).

Because the Exchange will no longer be adjusting the price of orders as provided for in Rule 7.31–E(a)(2)(C), the Exchange proposes that, generally, to prevent publishing a quote that would lock or cross an Away Market PBBO, following an Auction that is not preceded by continuous trading, if orders are marketable against protected quotations on Away Markets, routable orders would route and non-routable orders would cancel. To effect this change, the Exchange proposes to amend Rule 7.35–E(h)(3)(A)(ii) to provide that, before publishing a quote following a Trading Halt Auction (or Closing Auction if not preceded by continuous trading), previously-live orders would be processed as follows:

- Orders eligible to route that are marketable against protected quotations on Away Markets would route based on the ranking of such orders as set forth in Rule 7.36–E(c) (proposed Rule 7.35–E(h)(3)(A)(ii)(a)). With this proposed change, routable orders at potentially multiple price points would be routed to protected quotations on Away Markets before any other action is taken.
- After routing eligible orders, orders not eligible to route (excluding Primary Pegged Orders, and during a Short Sale Price Test, sell short orders) that are marketable against protected quotations on Away Markets would cancel (proposed Rule 7.35–E(h)(3)(A)(ii)(b)). The Exchange does not propose to route or cancel Primary Pegged Orders, or, during a Short Sale Price Test, sell short orders, because such orders, by their terms, are eligible to be repriced.
- Once there are no more unexecuted orders marketable against protected quotations on Away Markets (because they have either been routed or cancelled), orders that are marketable against other orders in the NYSE Arca Book would trade (proposed Rule 7.35–E(h)(3)(A)(ii)(c)). With this proposed step, remaining orders on the NYSE Arca book that could trade would trade.
- The display quantity of Reserve Orders would be replenished as provided for in Rule 7.31–E(d)(1) (proposed Rule 7.35–E(h)(3)(A)(ii)(d)).
- Primary Pegged Orders would be assigned a display price and working price as provided for in Rule 7.31–E, provided that such orders would cancel if the PBBO is locked or crossed or there is no PBB (PBO) against which to peg (proposed Rule 7.35–E(h)(3)(A)(ii)(e)). Because these orders reprice on arrival, the Exchange proposes to process previously-entered Primary Pegged Orders in the same manner following an Auction. This proposed rule text therefore makes clear that Primary Pegged Orders would be assigned a display price and working price no differently than they would on arrival, as described in Rule 7.31–E.
- Finally, sell short orders would be priced to a Permitted Price as provided for under Rule 7.16–E(f)(5) (proposed Rule 7.35–E(h)(3)(A)(ii)(f)). The Exchange proposes to reprice sell short orders last as the Permitted Price may have changed as a result of step one, described above (routing orders to the PBBO).

The Exchange believes that following a UTP Regulatory Halt or an Auction that is not preceded by continuous trading, orders that would lock or cross the Away Market PBBO should either be routed (if routable) or cancelled (if non-routable) if they would be marketable against protected quotations on Away Markets. The Exchange believes that routing or cancelling such orders is consistent with Rule 610(d) because the Away Market does not have an obligation to prevent locking or crossing an Exchange quote in these scenarios. Therefore, in these scenarios, to prevent locking or crossing the Away Market PBBO, the Exchange would either route or cancel previously-entered orders before publishing a quote. This was how the New York Stock Exchange LLC (''NYSE'') processed orders following an Auction before it transitioned to Pillar.

The Exchange also proposes a non-substantive change regarding how the term ''previously-live orders' is defined for purposes of Rule 7.35–E(h)(3)(A). Currently, the term ''previously-live orders'' is defined as unexecuted orders that were eligible to trade in the trading session both before and after the transition or auction. This definition is intended to refer to the trading session designated for an order, not that it was eligible to trade in continuous trading, and includes orders that were entered during a trading halt that occurred in the same trading session as the auction. To clarify this rule, the Exchange proposes to amend Rule 7.35E(h)(3)(A) and define a ''previously-live order'' as an unexecuted order that was received before the Auction Processing Period and was designated to trade in the trading session both before and after the transition or auction.

Third, the Exchange proposes to apply the proposed processing of orders, described above, to odd-lot orders. In other words, odd-lot orders would no longer be processed differently than orders that are a round lot or greater in size. Currently, Rule 7.38–E(b)(1) and subparagraphs (A)–(C) describe how the working and display price of odd-lot orders are adjusted in relation to the contra-side PBBO. In short, currently, the working and display prices of odd-lot orders are bound by the PBBO, which means that resting odd-lot orders can be repriced if the PBBO changes or becomes locked or crossed.[21]

As proposed, odd-lot sized orders would be priced the same as orders of a round-lot size or higher, and if they are designated Priority 2—Display Orders, they would stand their ground if locked or crossed by an Away Market PBBO. To effect this change, the Exchange proposes to delete Rule 7.38–E(b)(1) and sub-paragraphs (A)–(C) in their entirety. The Exchange also proposes to delete the clause ''provided that'' at the end of Rule 7.38–E(b) and make a non-substantive change to that Rule to replace the term ''in'' with the term ''on.'' As a result of these changes, Rule 7.38–E(b) would provide, without any qualifiers, that ''[r]ound lot, mixed lot and odd lot orders are treated in the same manner on the Exchange.'' The Exchange proposes an additional non-substantive change to renumber current Rule 7.38–E(b)(2) as Rule 7.38–E(c).

Fourth, because displayed odd-lot orders would stand their ground, the Exchange proposes to amend Rule 7.31–

[21] Current Rule 7.38–E(b)(1) provides that ''[t]he working and display price of an odd lot order will be adjusted both on arrival and when resting on the Exchange Book as follows: (A) If the limit price of an odd lot order to buy (sell) is at or below (above) the PBO (PBB), it will have a working and display price equal to the limit price. (B) If the limit price of an odd lot order to buy (sell) is above (below) the PBO (PBB), it will have a working price equal to the PBO (PBB). The display price will also be adjusted to the PBO (PBB) unless the order's instruction requires a display price that is different from the PBBO. (C) If the PBBO is locked or crossed and the limit price of an odd lot order to buy (sell) is above (below) the PBO (PBB), it will have a working and display price equal to the PBB (PBO). The working and display price of such odd lot order will not be adjusted again until the PBBO unlocks or uncrosses.''

E(d)(1) to add new subparagraph (F) relating to Reserve Orders to specify new functionality of how non-routable Reserve Orders would be replenished if the display quantity of a resting Reserve Order is decremented to an odd-lot size when the PBBO is crossed. The Exchange proposes this change only for non-routable Reserve Orders. These changes are not necessary for a routable Reserve Order because when such order replenishes, the replenish quantity is evaluated for routing to Away Markets and thus would not be displayed at a price that crosses an Away Market.

As proposed in new subparagraph (F) to Rule 7.31–E(d)(1), if the PBBO is crossed and the display quantity of a Reserve Order to buy (sell) that is a Non-Routable Limit Order is decremented to less than a round lot, the display price and working price of the remaining odd-lot quantity of the Reserve Order would not change. This proposed rule text is consistent with the change, described above, that resting displayed orders, including odd-lot sized orders, would stand their ground if crossed by an Away Market. The proposed rule would further provide that the reserve interest that replenishes the display quantity would be assigned a display price one MPV below (above) the PBO (PBB) and a working price equal to the PBO (PBB). Because this is the first time such interest would be displayed, the Exchange proposes to adjust the display and working price so that the replenished quantity would not lock or cross the Away Market, which is the same manner that an arriving Non-Routable Limit Order is priced.[22]

When the PBBO uncrosses, the display price and working price would be adjusted as provided for under paragraph (e)(1) of this Rule relating to Non-Routable Limit Orders.

Fifth, as described above, displayed orders would stand their ground if locked or crossed by an Away Market. However, non-displayed orders do not. As set forth in Rule 7.31–E(d)(2)(A), the working price of a resting Non-Displayed Limit Order will be adjusted based on the limit price of the order. If the limit price of a Non-Displayed Limit Order to buy (sell) is at or below (above) the PBO (PBB), it will have a working price equal to the limit price. If the limit price of a Non-Displayed Limit Order to buy (sell) is above (below) the PBO (PBB), it will have a working price equal to the PBO (PBB). The Exchange proposes to amend Rule 7.31–E(d)(1) to provide that the working price of the reserve interest of resting Reserve Orders, which are not displayed, would be adjusted in the same manner that the working price of Non-Displayed Limit Orders are adjusted.

To effect this change, the Exchange proposes to amend Rule 7.31–E(d)(1) to add the following sentence: ''The working price of the reserve interest of a resting Reserve Order will be adjusted in the same manner as a Non-Displayed Limit Order, as provided for in paragraph (d)(2)(A) of this Rule.'' The Exchange understands that at least one other exchange also adjusts the price of the non-displayed portion of Reserve Orders in the same manner that such exchange adjusts the price of non-displayed orders.[23]

Together with the proposed rule change described above to Rule 7.36–E(b), these rule changes make clear that on the Exchange, if crossed by an Away Market PBBO, displayed orders would stand their ground and non-displayed orders, including the reserve interest of resting Reserve Orders, would be repriced based off of the PBBO.

Implementation

Because of the technology changes associated with this proposed rule change, the Exchange will announce the implementation date of this proposed rule change by Trader Update. Subject to effectiveness of this proposed rule change, the Exchange anticipates that the implementation date will be in the Spring of 2020.

2. Statutory Basis

The Exchange believes that the proposal is consistent with Section 6(b) of the Act,[24] in general, and furthers the objectives of Sections 6(b)(5) of the Act,[25] in particular, because it is 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 mechanisms of, a free and open market and a national market system and, in general, to protect investors and the public interest and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that deleting Rule 7.31–E(a)(2)(C) and the related proposed amendment to Rule 7.36–E(b) to add new sub-paragraph (4) would remove impediments to and perfect the mechanism of a free and open market and a national market system because they would promote transparency in Exchange rules that previously-displayed orders would stand their ground if locked or crossed by an Away Market PBBO. The proposed rule changes would further promote transparency because they make clear that resting, displayed, depth-of-book orders that have been locked or crossed by an Away Market PBBO would be eligible to be disseminated to the SIP at their original price if they become the BBO.

The Exchange believes that previously-displayed orders, including depth-of-book orders, have priority at such price and should be able to stand their ground if locked or crossed by an Away Market. The Exchange therefore believes it is consistent with this principle to delete Rule 7.31–E(a)(2)(C) and change functionality on the Exchange for such orders to stand their ground and not be repriced if another market locks or crosses their price. The proposed change therefore benefits those resting orders because they would be able to keep their original working time and any priority ranking associated with such working time. The proposed change would also benefit liquidity takers, who would have greater certainty regarding the price at which they would receive an execution on the Exchange.

Moreover, the proposed change is consistent with how other exchanges function. While the rules of other exchanges differ in level of detail, these proposed changes are based in part on IEX Rules 11.190(h)(3)(A)(i) and (h)(3)(B)(i)and LTSE Rules 11.190(g)(3)(A)(i) and (g)(3)(B)(i), which similarly provide that previously-displayed orders on those exchanges maintain their display price and quantity if locked or crossed by an another market center. The proposal is also similar to how MEMX proposes it would function if approved as an exchange.

The Exchange further believes that these proposed amendments are consistent with Rule 610(d). If an Away Market publishes a PBBO that crosses

[22] *See* Rule 7.31–E(e)(1)(A) (describing how arriving Non-Routable Limit Order is priced). On Nasdaq, a Price to Comply Order with Reserve Size replenishes in a similar manner. *See* Nasdaq Rule 4703(h); *see also* Supplementary Material .02 to IEX Rule 11.190(h) (''When a reserve order refreshes its displayed portion, the refreshing shares are not permitted to be displayed at a price that locks or crosses the price of a protected quotation on an away market and are subject to display-price sliding'').

[23] *See* IEX Rule 11.190(b)(2) (stating that the non-displayed portion of reserve orders are treated as non-displayed orders). IEX reprices its non-displayed orders differently from how the Exchange reprices Non-Displayed Limit Orders. *See* IEX Rule 11.190(h)(3)(D). Importantly, both IEX and the Exchange reprice non-displayed orders when crossed by an Away Market PBBO.

[24] 15 U.S.C. 78f(b).

[25] 15 U.S.C. 78f(b)(5).

not only the Exchange's BBO, but also resting, displayed, depth-of-book orders, it was the Away Market that crossed previously-displayed orders. If such previously-displayed, depth-of-book orders become the Exchange's BBO, the Exchange believes it is appropriate to disseminate those previously-displayed prices and quantities to the SIP as the new BBO because those resting orders pre-existed the Away Market quote that locked or crossed them.

For the same reasons, the Exchange believes that the proposed changes to Primary Pegged Orders would remove impediments to and perfect the mechanism of a free and open market and a national market system because displayed orders that are pegged to a dynamic price would stand their ground at their original displayed price if locked or crossed by an Away Market, which is consistent with the proposed rule change that all displayed orders would stand their ground. These proposed rule changes also promote transparency by specifying that such orders would continue to be eligible to trade at their original working price, and that their display and working prices would not be adjusted until the PBBO is no longer locked or crossed.

The Exchange further believes that routing or cancelling orders that are marketable against an Away Market PBBO following a UTP Regulatory Halt or an Auction that is not preceded by continuous trading would also remove impediments to and perfect the mechanism of a free and open market and a national market system because in these scenarios, the Away Market would not have had an obligation to prevent displaying a locking or crossing quotation. The Exchange proposes to avoid locking or crossing an Away Market PBBO in these scenarios by routing or cancelling previously-displayed orders, as applicable. These proposed changes would reduce the number of times resting orders would be repriced, thereby increasing determinism for the price at which orders would be executed on the Exchange. The Exchange notes that this proposed change is not novel as this is how NYSE processed orders following an auction before it transitioned NYSE-listed securities to Pillar. The Exchange further believes that the proposed change to the definition of ''previously-live orders'' would remove impediments to and perfect the mechanism of a free and open market and a national market system because the proposed rule text is designed to clarify the existing rule without changing its meaning, thus promoting transparency and clarity in Exchange rules.

The Exchange believes that processing odd-lot sized orders in the same manner as round-lot sized orders would remove impediments to and perfect the mechanism of a free and open market because the same principle applies: An order of any size that has been displayed has priority at that price if an Away Market subsequently locks or crosses that price. In addition, the Exchange believes that processing odd-lot orders the same as round-lot sized orders is not novel as it is consistent with the rules of other exchanges.[26]

Finally, the Exchange believes that the proposed changes to Reserve Orders would remove impediments to and perfect the mechanism of a free and open market because it would apply these principles to a Non-Routable Limit Order that is also a Reserve Order. This proposed functionality is also consistent with how Nasdaq and IEX process non-routable orders with reserve interest.[27] The proposed change to reprice the reserve interest of resting Reserve Orders in the same manner as a Non-Displayed Limit Order is priced would also remove impediments to and perfect the mechanism of a free and open market because it would promote consistency in Exchange rules regarding how similar orders are priced when crossed by an Away Market. The proposed change is also consistent with how IEX processes the reserve interest of Reserve Orders.[28]

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[29] the Exchange believes that the proposed rule change would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed change is competitive because it is designed to conform how the Exchange processes previously-displayed orders with the functionality available on other exchanges, *i.e.,* that such orders would stand their ground if locked or crossed by an Away Market and be eligible to be disseminated to the SIP at their original price. The Exchange believes that the proposed change would promote competition because fewer orders would need to be repriced on the Exchange and therefore liquidity providers seeking for their orders to retain priority may route additional orders to the Exchange. Likewise, liquidity takers may be more likely to route orders to the Exchange if they have greater determinism regarding the price at which their orders would be executed.

Without this proposed rule change regarding how displayed orders would stand their ground if locked or crossed by an Away Market, the Exchange is currently at a competitive disadvantage vis-à-vis all other equity exchanges, which do not reprice orders in this manner. As discussed above, displayed orders on all other equity exchanges, including the two exchanges that recently had their Form 1 applications to be approved as an exchange (IEX and LTSE), stand their ground when locked or crossed by an Away Market and such orders are disseminated to the SIP if they become those exchanges' best bid or offer. In addition, MEMX proposes that displayed orders would stand their ground if locked or crossed by an Away Market.

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:

[26] *See, e.g.,* Nasdaq Rules 4703(b)(3) (defining the term ''odd lot'' as an order attribute) and 4702 (describing which order attributes are available for orders on Nasdaq, without any discussion of odd-lot sized orders being priced differently than round-lot sized orders). *See also* BZX Rules 11.10 (defining the term ''odd lot'') and 11.9 (describing BZX Orders and Modifiers, without any discussion of odd-lot sized orders being priced differently than round-lot sized orders).

[27] *See supra* note 22.

[28] *See supra* note 23.

[29] 15 U.S.C. 78f(b)(8).

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–2020–17 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca-2020–17. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*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 offices 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–2020–17, and should be submitted on or before April 8, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[30]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–05557 Filed 3–17–20; 8:45 am]

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[30] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–88374; File No. SR–Phlx–2020–08]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Certain Phlx Rules To Remove References to Mini Options

March 12, 2020,

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 March 5, 2020, Nasdaq PHLX LLC (''Phlx'' or ''Exchange'') 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 the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Phlx Rules at Options 3, Section 3, Minimum Increments, Section 12, Electronic Qualified Contingent Cross Order, Section 13, Price Improvement XL (''PIXL''), Section 14, Complex Orders; Options 4, Section 5, Series of Options Open for Trading; Options 7, Section 1, General Provisions, Section 6, Other Transaction Fees; Options 8, Section 24, Bids And Offers—Premium, Section 30, Crossing, Facilitation and Solicited Orders; and Options 9, Section 13, Position Limits to remove references to Mini Options.

The text of the proposed rule change is available on the Exchange's website at *http://nasdaqphlx.cchwallstreet.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 Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Phlx Rules at Options 3, Section 3, Minimum Increments, Section 12, Electronic Qualified Contingent Cross Order, Section 13, Price Improvement XL (''PIXL''), Section 14, Complex Orders; Options 4, Section 5, Series of Options Open for Trading; Options 7, Section 1, General Provisions, Section 6, Other Transaction Fees; Options 8, Section 24, Bids And Offers—Premium, Section 30, Crossing, Facilitation and Solicited Orders; and Options 9, Section 13, Position Limits to remove references to Mini Options.

The Exchange has not listed Mini Options in several years and is proposing to delete listing rules and other ancillary trading rules related to the listing of Mini Options. The Exchange notes that it has no open interest in Mini Options.

Specifically, the Exchange proposes to amend the following Phlx Rules: Options 3, Section 3, Minimum Increments, Section 12, Electronic Qualified Contingent Cross Order, Section 13, Price Improvement XL (''PIXL''), Section 14, Complex Orders; Options 4, Section 5, Series of Options Open for Trading; Options 7, Section 1, General Provisions, Section 6, Other Transaction Fees; Options 8, Section 24, Bids And Offers—Premium, Section 30, Crossing, Facilitation and Solicited Orders; and Options 9, Section 13, Position Limits, to remove references to Mini Options in the System as well as the pricing of Mini Options executed on Phlx. In the event that the Exchange desires to list Mini Options in the future, it would file a rule change with the Commission to adopt rules to list Mini Options.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[3] in general, and furthers the objectives of Section 6(b)(5) of the Act,[4] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78f(b).

[4] 15 U.S.C. 78f(b)(5).

system, and, in general to protect investors and the public interest.

The Exchange's proposal to removal references to the listing and handling of Mini Options is consistent with the Act because Mini Options have not been listed in several years and thereby removing the references to the rules would render the rules more accurate and reduce potential investor confusion. Also, the Exchange notes that it has no open interest in Mini Options. In the event that the Exchange desires to list Mini Options in the future, it would file a rule change with the Commission to adopt rules to list Mini Options.

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 not necessary or appropriate in furtherance of the purposes of the Act. The Exchange's proposal to removal references to the listing and handling of Mini Options do not impose an undue burden on competition. Mini Options have not been listed in several years. Also, the Exchange notes that it has no open interest in Mini Options.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act [5] and subparagraph (f)(6) of Rule 19b–4 thereunder.[6]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–Phlx–2020–08 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–Phlx–2020–08. 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–Phlx–2020–08 and should be submitted on or before April 8, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–05560 Filed 3–17–20; 8:45 am]

BILLING CODE 8011–01–P

[5] 15 U.S.C. 78s(b)(3)(A)(iii).

[6] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[7] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–88372; File No. SR–CBOE–2020–017]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Rules Related to the Automated Improvement Mechanism and Complex Automated Improvement Mechanism

March 12, 2020.

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 March 10, 2020, Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') proposes to amend its rules related to the Automated Improvement Mechanism and Complex Automated Improvement Mechanism. 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://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), 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

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its rules related to the Automated Improvement Mechanism (''AIM'') and Complex Automated Improvement Mechanism (''C–AIM'') to (1) allow auction periods to be set on a class-by-class basis and (2) increase the maximum allowable duration of the respective auction periods.

By way of background, Rule 5.37 contains the requirements applicable to the execution of orders using AIM and Rule 5.38 contains the requirements applicable to the execution of complex orders using C–AIM. AIM and C–AIM allow the Exchange's Trading Permit Holders (''TPHs'') to electronically cross orders on the Exchange's System. Specifically, AIM and C–AIM allow TPHs to designate certain orders for price improvement and submit such orders into AIM and C–AIM with a matching facilitated or solicited contra order. Once the order is properly submitted, the Exchange commences an auction by sending a message to all TPHs who have elected to receive AIM and C–AIM auction notification messages. Pursuant to current Rules 5.37(c)(3) and 5.38(c)(3), orders entered into AIM and C–AIM, respectively, are exposed for a period of time (the ''AIM Auction Period'' and ''C–AIM'' Auction Period'', respectively) that may be determined by the Exchange and which may be no less than 100 milliseconds and no more than one second.

The Exchange first proposes to provide in Rules 5.37(c)(3) and 5.38(c)(3) that the Exchange may determine the duration of the AIM and C–AIM Auction Periods on a ''class-by-class basis'' to provide the Exchange additional flexibility. The Exchange notes that trading characteristics, market models, and investor base may differ between options classes and that such differences may necessitate different auction periods be set for certain classes. The Exchange believes the proposed rule change ensures the Exchange to can appropriately address these differences. Moreover, the Exchange notes that the Exchange is able to set the duration of an auction period on a class-by-class basis for another auction mechanism under its rules (*i.e.,* the Complex Order Auction (''COA'').[3]

The Exchange next proposes to amend the maximum allowable duration of the AIM and C–AIM Auction Periods. As indicated above, the AIM and C–AIM Auction Periods may not be less than 100 milliseconds or more than one second. The Exchange believes that it is in TPHs' best interest to minimize the response timer to a time frame that continues to allow adequate time for the TPHs to respond to a AIM or C–AIM auction message, as both the order being exposed and the TPHs responding are subject to market risk during the response timer period. Indeed, the Exchange notes its timer is currently set at the minimum 100 milliseconds. However, the Exchange also notes that there may be instances which require a longer auction period. For example, during times of extreme market volatility, TPHs may require additional time to submit their responses and/or such market volatility may result in a significant increase in message traffic, which could potentially result in a delay of processing of AIM and C–AIM auction responses. In such instances, the Exchange believes an auction period of the current maximum of 1 second may be inadequate. As such, to ensure participants can respond to, and the system can process, AIM and C–AIM auction responses in a sufficient amount of time, the Exchange proposes to increase the maximum AIM and C–AIM Auction Period duration from 1 second to 3 seconds (*i.e.,* 3000 milliseconds). The Exchange notes the proposed maximum is the same as the maximum allowed for the auction period for COA.[4]

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[5] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[6] 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. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[7] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The proposed rule change to allow the Exchange to set the AIM and C–AIM Auction Period on a class-by-class basis provides the Exchange the flexibility to set the duration of the auction periods to address the specific characteristics of a class and its market, thereby protecting investors by removing impediments to and perfecting the mechanisms of a free and open market and a national market system. Additionally, the Exchange notes that it has flexibility to set times on a class-by-class basis under its rules for another auction mechanism, COA.[8]

The Exchange believes the proposal to increase the maximum AIM and C–AIM Auction Period from 1 second to 3 seconds promotes just and equitable principles of trade and removes impediments to a free and open market because it allows the Exchange to provide increased time for Trading Permit Holders participating in a AIM or C–AIM auction to submit auction responses and have such responses processed by the Exchange in a timely manner, which could encourage competition among participants, thereby enhancing the potential for price improvement for orders in AIM and C–AIM to the benefit of investors and public interest. The Exchange believes the proposed rule change is not unfairly discriminatory because it establishes a maximum auction period applicable to all Exchange participants participating in AIM or C–AIM. The Exchange also notes the proposed maximum timer is the same as the timer allowed by the Exchange for another auction mechanism, COA.[9]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The

[3] *See* Rule 5.33(d)(3).

[4] *Id.*

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(5).

[7] *Id.*

[8] *See* Rule 5.33(d)(3).

[9] *Id.*

proposed rule changes are not intended as a competitive filing. Rather, the proposed rule change to allow the auction periods to be set on a class-by-class basis is designed to provide the Exchange flexibility so that it may address specific needs and characteristics of each class with respect to the AIM and C–AIM Auction Periods. The proposed change to increase the maximum AIM and C–AIM Auction Periods is also not designed to address any aspect of competition, but instead would continue to provide market participants with sufficient time to respond, compete, and provide price improvement for orders entered into AIM or C–AIM. The proposed rule change merely increases the auction period maximum (which matches a maximum already allowed for COA) to provide the Exchange further flexibility to ensure Trading Permit Holders have sufficient time to submit, and the Exchange has sufficient time to process, AIM and C–AIM responses. The proposed rule change also offers the same auction period to all TPHs and would not impose a competitive burden on any particular participant.

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

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act [10] and subparagraph (f)(6) of Rule 19b–4 thereunder.[11]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act [12] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii) [13] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. The Exchange represents that waiver of the operative delay would add rule text that was omitted from the post-migration Rulebook and reinstate a maximum Response Time Interval that was in place pre-migration. The Exchange states that in times of extreme market volatility, there may be increased message traffic which could potentially result in a delay of processing of COA responses, and the proposed change would help ensure that participants can respond to (and the exchange's systems can process) COA responses in a sufficient amount of time. The Commission notes that the proposed rule change does not present any unique or novel regulatory issues. Accordingly, the Commission hereby waives the operative delay and designates the proposal operative upon filing.[14]

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: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml);* or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CBOE–2020–017 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–CBOE–2020–017. 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–CBOE–2020–017 and should be submitted on or before April 8, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–05558 Filed 3–17–20; 8:45 am]

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[10] 15 U.S.C. 78s(b)(3)(A)(iii).

[11] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Commission has waived the five-day prefiling requirement in this case.

[12] 17 CFR 240.19b–4(f)(6).

[13] 17 CFR 240.19b–4(f)(6)(iii).

[14] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[15] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–88376; File No. SR–NYSE–2020–17]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing of Proposed Rule Change To Amend its Rules To Add New Rule 7.19

March 12, 2020.

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 March 10, 2020, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its rules to add new Rule 7.19 (Pre-Trade Risk Controls). The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

In order to assist member organizations' efforts to manage their risk, the Exchange proposes to amend its rules to add new Rule 7.19 (Pre-Trade Risk Controls) to establish a set of pre-trade risk controls by which Entering Firms and their designated Clearing Firms (as defined below) may set credit limits and other pre-trade risk controls for an Entering Firm's trading on the Exchange and authorize the Exchange to take action if those credit limits or other pre-trade risk controls are exceeded.[4]

For purposes of this proposed rule change, the Exchange proposes to define the term ''Entering Firm'' to mean a member organization that either has a correspondent relationship with a Clearing Firm whereby it executes trades and the clearing function is the responsibility of the Clearing Firm or clears for its own account [5] and to define the term ''Clearing Firm'' to mean a member organization that acts as principal for clearing and settling a trade, whether for its own account or for an Entering Firm.[6]

1. Overview

In order to help firms manage their risk, the Exchange proposes to offer optional pre-trade risk controls that would authorize the Exchange to take automated actions if a designated credit limit or other pre-trade risk control for a firm is breached. Because Clearing Firms bear the risk on behalf of their correspondent Entering Firms, the Exchange proposes to make the proposed pre-trade risk controls available not only to Entering Firms, but also to their Clearing Firms, if so authorized by the Entering Firm. These pre-trade risk controls would provide Entering Firms and their Clearing Firms with enhanced abilities to manage their risk with respect to orders on the Exchange.

As proposed, these optional controls would allow Entering Firms and their Clearing Firms (if designated by the Entering Firm) to each define different pre-set risk thresholds and to choose the automated action the Exchange would take if those thresholds are breached, which would range from notifying the Entering Firm and Clearing Firm that a limit has been breached, blocking new orders, or canceling orders until the Entering Firm has been reinstated to trade on the Exchange.

Although use of the proposed Exchange-provided pre-trade risk controls are optional, all orders on the Exchange will pass through risk checks. As such, an Entering Firm that does not choose to set limits or permit its Clearing Firm to set limits on its behalf will not achieve any latency advantage with respect to its trading activity on the Exchange. In addition, the Exchange expects that any latency added by the pre-trade risk controls will be *de minimis.*

The proposed pre-trade risk controls described are meant to supplement, and not replace, the member organizations' own internal systems, monitoring and procedures related to risk management. The Exchange does not guarantee that these controls will be sufficiently comprehensive to meet all of a member organization's needs, the controls are not designed to be the sole means of risk management, and using these controls will not necessarily meet a member organization's obligations required by Exchange or federal rules (including, without limitation, the Rule 15c3–5 under the Act [7] (''Rule 15c3–5'')). Use of the Exchange's pre-trade risk controls will not automatically constitute compliance with Exchange or federal rules and responsibility for compliance with all Exchange and SEC rules remains with the member organization.[8]

2. Proposed Rule Change

Proposed Rule 7.19(a) would set forth the definitions that would be used for purposes of the Rule. In addition to the defined terms of ''Entering Firm'' and ''Clearing Firm,'' as described above, the Exchange proposes the following definitions:

- The term ''Single Order Maximum Notional Value Risk Limit'' would mean a pre-established maximum dollar amount for a single order before it can be traded.
- The term ''Single Order Maximum Quantity Risk Limit'' would mean a pre-established maximum number of shares

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] The Exchange initially filed a proposed rule change to add new Rule 7.19 relating to pre-trade risk controls on November 27, 2019. *See* Securities Exchange Act Release No. 87715 (December 11, 2019), FR (date) (Notice of Filing) (SR–NYSE–2019–68) (''Original Filing''). The Exchange withdrew the Original Filing and is filing this proposed rule change as its replacement. This filing is substantially the same as the Original Filing and proposes the same functionality. It differs because it includes proposed Commentary .02 through .04, which provides additional detail specific to Floor brokers and Designated Market Makers, and makes minor, clarifying changes to the proposed rule text as compared to the Original Filing.

[5] *See* proposed Rule 7.19(a)(1).

[6] *See* proposed Rule 7.19(a)(2). As required by Rule 7.14, a member organization is required to give up the name of the clearing firm through which each transaction on the Exchange will be cleared.

[7] *See* 17 CFR 240.15c3–5.

[8] The Exchange proposes Commentary .01 to Rule 7.19 to provide that ''[t]he pre-trade risk controls described in this Rule are meant to supplement, and not replace, the member organization's own internal systems, monitoring and procedures related to risk management and are not designed for compliance with Rule 15c3–5 under the Exchange Act. Responsibility for compliance with all Exchange and SEC rules remains with the member organization.''

that may be included in a single order before it can be traded.

• The term ''Gross Credit Risk Limit'' would mean a pre-established maximum daily dollar amount for purchases and sales across all symbols, where both buy and sell orders are counted as positive values. For purposes of calculating the Gross Credit Risk Limit, unexecuted orders in the Exchange Book,[9] orders routed on arrival pursuant to Rule 7.37(a)(1), and executed orders are included.

Proposed Rule 7.19(b) would set forth the Pre-Trade Risk Controls that would be available to Entering Firms and Clearing Firms. Under proposed Rule 7.19(b)(1), an Entering Firm may select one or more of the following optional pre-trade risk controls with respect to its trading activity on the Exchange: (i) Gross Credit Risk Limits; (ii) Single Order Maximum Notional Value Risk Limits; and (iii) Single Order Maximum Quantity Risk Limits, which would collectively be referred to as the ''Pre-Trade Risk Controls.''

In addition, under proposed Rule 7.19(b)(2)(A), an Entering Firm that does not self-clear may designate its Clearing Firm to (i) view any Pre-Trade Risk Controls set by the Entering Firm, or (ii) set one or more Pre-Trade Risk Controls on the Entering Firm's behalf, or both. Proposed Rule 7.19(b)(2)(B) provides that an Entering Firm would be able to view any Pre-Trade Risk Controls that its Clearing Firm sets with respect to the Entering Firm's trading activity on the Exchange. Because both an Entering Firm and Clearing Firm (if so designated by the Entering Firm) would be able to access information about Pre-Trade Risk Controls, this mechanism would foster transparency between an Entering Firm and its Clearing Firm regarding which Pre-Trade Risk Control limits may have been set. For example, if an Entering Firm designates its Clearing Firm to view the Pre-Trade Risk Controls set by that Entering Firm, its Clearing Firm may determine that it does not need to separately set Pre-Trade Risk Controls on behalf of such Entering Firm.

Because the Entering Firm is the member organization that is entering orders on the Exchange, the Exchange will not take action based on a Clearing Firm's instructions about the Entering Firm's trading activities on the Exchange without first receiving consent from the Entering Firm. Accordingly, proposed Rule 7.19(b)(2)(C) would provide that if an Entering Firm designates a Clearing Firm to set Pre-Trade Risk Controls for the Entering Firm, the Entering Firm would be consenting to the Exchange taking certain prescribed actions (discussed further below) with respect to the Entering Firm's trading activity as provided for in proposed Rules 7.19(c) and (d), described below. The Exchange would consider an Entering Firm to provide such consent by authorizing a Clearing Firm to enter Pre-Trade Risk Controls via the risk management tool that will be provided to Entering Firms in connection with this proposed rule change. Once such authorization is provided by the Entering Firm, the Clearing Firm would have access to the Pre-Trade Risk Controls that the Entering Firm designates. The proposed Rule makes clear that by designating a Clearing Firm to set limits on its trading activities, the Entering Firm will have authorized the Exchange to act pursuant to the Clearing Firm's instructions if the limits set by the Clearing Firm are breached.

Proposed Rule 7.19(b)(3) would set forth how the Pre-Trade Risk Controls could be set or adjusted. Proposed Rule 7.19(b)(3)(A) would provide that Pre-Trade Risk Controls may be set before the beginning of a trading day and may be adjusted during the trading day. Proposed Rule 7.19(b)(3)(B) would provide that Entering Firms or Clearing Firms may set Pre-Trade Risk Controls at the MPID level or at one or more sub-IDs associated with that MPID.[10] The Exchange believes that supporting Pre-Trade Risk Controls at both an MPID and sub-ID level would provide both Entering Firms, and if designated, their Clearing Firms, more granular control over how such risk controls are determined and monitored.

Proposed Rule 7.19(b)(4) would provide that with respect to Gross Credit Risk Limits, an Entering Firm and, if so designated, its Clearing Firm, will receive notifications when the Entering Firm is approaching or has breached a limit set by itself or by the Clearing Firm. The Exchange believes that by providing such notifications, the Entering Firm, and if designated, its Clearing Firm, would have advance notice that the Entering Firm is approaching a designated limit and could take steps to mitigate the potential that an automated breach action would be triggered.

Proposed Rule 7.19(c) would set forth the actions the Exchange would be authorized to take when a Pre-Trade Risk Control set by an Entering Firm or a Clearing Firm is breached, which would be referred to as ''Automated Breach Actions.'' These proposed actions would be automated; if a Pre-Trade Risk Control is breached, the Exchange would automatically take the designated action and would not need further direction from either the Entering Firm or Clearing Firm to take such action.

At the outset, proposed Rule 7.19(c)(1) would provide that if both an Entering Firm and its Clearing Firm set the same type of Pre-Trade Risk Control for the Entering Firm but have set different limits, the Exchange would enforce the more restrictive limit. For example, if an Entering Firm sets a Single Order Maximum Notional Value Risk Limit of $20 million and its Clearing Firm sets the same risk limit at $15 million, the Exchange will take action when the more restrictive limit is breached—*i.e.,* $15 million.

Proposed Rule 7.19(c)(2) would set forth the Automated Breach Action the Exchange would take if an order would breach the designated limit of either a Single Order Maximum Notional Value Risk Limit or Single Order Maximum Quantity Risk Limit. As proposed, the Exchange would reject the incoming order that would have breached the applicable limit.

Proposed Rule 7.19(c)(3)(A) would set forth the Automated Breach Actions the Exchange would take if a designated Gross Credit Risk Limit is breached. The Exchange proposes to provide options of which Automated Breach Action the Exchange would be authorized to take if a Gross Credit Risk Limit is breached. Such Automated Breach Actions would be taken at the MPID or sub-ID level that is associated with the designated Gross Credit Risk Limit. As proposed, when setting Gross Credit Risk Limits, the Entering Firm or Clearing Firm setting the limit would be required to indicate one of the following actions that the Exchange would take if such limit is breached:

• ''Notification Only.'' As set forth in proposed Rule 7.19(c)(3)(A)(i), if this option is selected, the Exchange would continue to accept new orders and order instructions and would not cancel any unexecuted orders in the Exchange Book. Proposed Rule 7.19(b)(4), described above, sets forth the notifications that would be provided to an Entering Firm, and if designated, a Clearing Firm regarding the Pre-Trade Risk Controls that have been set. With the ''Notification Only'' action, the

[9] The term ''Exchange Book'' is defined in Rule 1.1(k) to refer to the Exchange's electronic file of orders, which contains all orders entered on the Exchange.

[10] Entering Firms may request that the Exchange create sub-IDs associated with their MPIDs. If an Entering Firm uses a Floor broker to enter orders on the Exchange, it can assign a sub-ID that would be used for the entry of orders by that Floor broker on the Entering Firm's behalf.

Exchange would provide such notifications, but would not take any other automated actions with respect to new or unexecuted orders.

• ''Block Only.'' As set forth in proposed Rule 7.19(c)(3)(A)(ii), if this option is selected, the Exchange would reject new orders and order instructions but would not cancel any unexecuted orders in the Exchange Book. The Exchange would continue to accept instructions from the Entering Firm to cancel one or more orders in full (including Auction-Only Orders) or any instructions specified in proposed Rule 7.19(e) (described below), but would not take any automated action to cancel orders.

• ''Cancel and Block.'' As set forth in proposed Rule 7.19(c)(3)(A)(iii), if this option is selected, in addition to the Block actions described above, the Exchange would also cancel all unexecuted orders in the Exchange Book other than Auction-Only Orders.

If an Entering Firm and its Clearing Firm each set different limits for a Gross Credit Risk Limit for the Entering Firm's activities on the Exchange, proposed Rule 7.19(c)(3)(B) would provide that the Exchange would enforce the action that was chosen by the party that set the limit that was breached. For example, if a Clearing Firm sets a lower limit and designates the ''Cancel and Block'' Automated Breach Action, if that limit is breached, the Exchange will implement that ''Cancel and Block'' action even if the Entering Firm designated a different Automated Breach Action.

Proposed Rule 7.19(c)(3)(C) would provide that if both the Entering Firm and Clearing Firm set the same Gross Credit Risk Limit and that limit is breached, the Exchange would enforce the most restrictive Automated Breach Action. As further proposed, for purposes of this Rule, the ''Cancel and Block'' action would be more restrictive than ''Block Only,'' which would be more restrictive than ''Notification Only.'' For example, if the Entering Firm selects the ''Block Only'' action for a Gross Credit Risk Limit and its Clearing Firm selects the ''Cancel and Block'' action for the same Gross Credit Risk Limit, if the limit is breached, the Exchange would take the ''Cancel and Block'' action for the Entering Firm's orders.

Proposed Rule 7.19(c)(4) would provide that if a Pre-Trade Risk Control set at the MPID level is breached, the Automated Breach Action specified at the MPID level would be applied to all sub-IDs associated with that MPID. For instance, if a Clearing Firm sets a Gross Credit Risk Limit for an MPID at $500 million and the Entering Firm sets Gross Credit Risk Limits for each of three sub-IDs associated with that MPID at $500 million each, if two of the sub-IDs reach a $250 million limit, which combined is the Gross Credit Risk Limit at the MPID level, the Automated Breach Action associated with the limit at the MPID level would be triggered and would apply also to the associated sub-IDs, even though none of the sub-IDs have breached their separate $500 million limits. This functionality ensures that an Entering Firm cannot effectively override a Pre-Trade Risk Control set at the MPID level by setting risk limits for each of the MPID's associated sub-IDs that cumulatively equal more than the MPID's total Gross Credit Risk Limit.

Proposed Rule 7.19(d) concerns how an Entering Firm's ability to enter orders and order instructions would be reinstated after a ''Block Only'' or ''Cancel and Block'' Automated Breach Action has been triggered. In such case, proposed Rule 7.19(d) provides that the Exchange would not reinstate the Entering Firm's ability to enter orders and order instructions on the Exchange (other than instructions to cancel one or more orders (including Auction-Only Orders) in full) without the consent of (1) the Entering Firm, and (2) the Clearing Firm, if the Entering Firm has designated that the Clearing Firm's consent is required. The Exchange proposes to include this functionality because the Clearing Firm bears the risk of any exposure of its correspondent Entering Firms.

Finally, proposed Rule 7.19(e) would set forth ''kill switch'' functionality, which would allow an Entering Firm or its designated Clearing Firm to direct the Exchange to take certain bulk Kill Switch Actions with respect to orders. In contrast to the Automated Breach Actions described above, which the Exchange would take automatically after the breach of a credit limit, the Exchange would not take any of the Kill Switch Actions without express direction from the Entering Firm or its designated Clearing Firm.

Specifically, Proposed Rule 7.19(e) would specify that an Entering Firm, or if authorized pursuant to proposed Rule 7.19(b)(2)(A), its Clearing Firm, could direct the Exchange to take one or more of the following actions with respect to orders at either an MPID, or if designated, sub-ID Level: (1) Cancel all Auction-Only Orders; (2) Cancel all unexecuted orders in the Exchange Book other than Auction-Only Orders; or (3) Block the entry of any new orders and order instructions, provided that the Exchange would continue to accept instructions from Entering Firms to cancel one or more orders (including Auction-Only Orders) in full, and later, reverse that block.

The Exchange proposes that the Kill Switch functionality proposed in Rule 7.19(e) would supersede and replace the Exchange's previously filed proposed rule change (the ''2013 Risk Control Filing''),[11] which provided certain post-trade risk management tools to member organizations, but not to their Clearing Firms.

The Exchange proposes to provide these post-trade Kill Switch Actions in addition to the pre-trade Automated Breach Actions described above in order to give Entering Firms and their Clearing Firms more flexibility in setting risk controls. An Entering Firm that wants more control over when and which actions are taken with respect to its orders may choose to use these Kill Switch Actions instead of the ''Block'' or ''Cancel and Block'' Automated Breach Actions described above. For example, for an Entering Firm that selects the ''Notification Only'' Automated Breach Action, if it receives notification of a credit breach, it could choose to direct the Exchange to take a Kill Switch Action described in proposed Rule 7.19(e).

3. Proposed Rule Commentary

The Exchange proposes Commentary .01 to Rule 7.19 to specify that the Pre-Trade Risk Controls described in this Rule are meant to supplement, and not replace, the member organization's own internal systems, monitoring and procedures related to risk management and are not designed for compliance with Rule 15c3–5 under the Act (''Rule 15c3–5'').[12] This proposed Commentary specifies that use of the Exchange's pre-trade risk controls would not automatically constitute compliance with Exchange or federal rules and responsibility for compliance with all Exchange and SEC rules remains with the member organization. The Exchange does not guarantee that these controls will be sufficiently comprehensive to meet all of a member organization's needs, the controls are not designed to be the sole means of risk management, and using these controls will not necessarily meet a member organization's obligations required by Exchange or federal rules (including, without limitation, the Rule 15c3–5).

Proposed Commentary .02 would provide that when a customer of a Floor

[11] *See* Securities Exchange Act Release No. 71164 (December 20, 2013), 78 FR 79044 (December 27, 2013) (SR–NYSE–2013–80) (Notice of filing and immediate effectiveness of proposed rule change) (the ''2013 Risk Control Filing'').

[12] *See* 17 CFR 240.15c3–5.

broker firm is a member organization (''Customer''), both the Customer and the Floor broker firm would be considered an ''Entering Firm'' for purposes of setting Pre-Trade Risk Controls or Kill Switch Actions for that Floor broker's trading activity on the Exchange on behalf of that Customer. There would be no differences in the Pre-Trade Risk Controls available to the Customer and Floor broker.

Proposed Commentary .03 would provide that manual transactions by a Floor broker and crossing transactions pursuant to Rule 76 will be excluded from Pre-Trade Risk Controls. The Exchange proposes this exception because the proposed Pre-Trade Risk Controls would be incorporated into the Exchange's matching engine systems, and neither manual transactions nor crossing transactions pursuant to Rule 76 are processed in such systems. Floor brokers representing such orders would continue to have their independent obligation to comply with Rule 15c3–5 with respect to these orders.

Proposed Commentary .04 would specify how the proposed Pre-Trade Risk Controls would apply to Designated Market Makers (''DMMs'') on the Exchange. The proposed commentary would provide that if either a ''Block Only'' or a ''Cancel and Block'' Automated Breach Action has been triggered by an Entering Firm acting as a DMM in an assigned security, such DMM would be prevented from facilitating an auction that would include any DMM Interest, as defined in Rule 7.35(a)(8).[13] If the DMM has not yet been reinstated, the DMM can facilitate an auction if it does not include DMM Interest. This restriction would apply whether the DMM attempted to facilitate the auction electronically or manually; if the DMM attempted to electronically facilitate the auction and include DMM Interest, the Exchange would reject the attempt. However, the DMM would still have an opportunity to facilitate such auction manually without DMM Interest. The Exchange anticipates that a DMM will set Gross Credit Risk Limits at levels that would not result in Automated Breach Actions, and if they do trigger a ''Block Only'' or a ''Cancel and Block'' Automated Breach Action, they would promptly reinstate themselves to avoid such a situation.

[13] DMMs have an affirmative obligation to facilitate openings, reopenings, and the close of trading for each of the securities in which the DMM is registered as required by Exchange rules. *See* Rule 104(a)(2) and (3).

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[14] in general, and furthers the objectives of Section 6(b)(5) of the Act,[15] in particular, because it is 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 because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

Specifically, the Exchange believes that the proposed rule will remove impediments to and perfect the mechanism of a free and open market and a national market system because the proposed optional Pre-Trade Risk Controls would provide both Entering Firms, and if designated, Clearing Firms, with the ability to manage risk, while also providing an alert system that would help to ensure that such firms are aware of developing issues. In addition, the Pre-Trade Risk Controls would provide Clearing Firms, who have assumed certain risks of the Entering Firms, greater control and flexibility over setting risk tolerance and exposure on behalf of their correspondent Entering Firms. As such, the Exchange believes that the Pre-Trade Risk Controls would provide a means to address potentially market-impacting events, helping to ensure the proper functioning of the market.

In addition, the Exchange believes that the proposed rule change is designed to protect investors and the public interest because the Pre-Trade Risk Controls are a form of impact mitigation that will aid Entering Firms and Clearing Firms in minimizing their risk exposure and reduce the potential for disruptive, market-wide events. The Exchange understands that member organizations implement a number of different risk-based controls, including those required by Rule 15c3–5. The proposed controls will serve as an additional tool for Entering Firms and Clearing Firms to assist them in identifying any risk exposure. The Exchange believes the Pre-Trade Risk Controls will assist Entering Firms and Clearing Firms in managing their financial exposure which, in turn, could enhance the integrity of trading on the securities markets and help to assure the stability of the financial system.

Further, the Exchange believes that the proposed rule will foster cooperation and coordination with persons facilitating transactions in securities because the Exchange will provide alerts to Entering Firms and their Clearing Firms when the Entering Firm's trading reaches certain thresholds. As such, the Exchange will help Clearing Firms monitor the risk levels of their correspondent Entering Firms and provide tools for Clearing Firms, if designated, to take action.

The Exchange believes that proposed Commentary .01 to Rule 7.19 is designed to prevent fraudulent and manipulative acts and practices and promote just and equitable principles of trade because it provides clarity in Exchange rules that the proposed Pre-Trade Risk Controls are intended to supplement, and not replace, a member organization's own internal systems, monitoring, and procedures related to compliance with Rule 15c3–5.

The Exchange believes that proposed Commentary .02 and .03 to Rule 7.19 would remove impediments to and perfect the mechanism of a free and open market and a national market system because they provide clarity regarding how the Pre-Trade Risk Controls would be available to both Floor brokers and their Customers and that the proposed controls would not be available for specified order types that are not processed by the matching engine.

The Exchange similarly believes that proposed Commentary .04 would remove impediments to and perfect the mechanism of a free and open market and a national market system because it promotes transparency and clarity in Exchange rules that DMMs would be able to continue to facilitate auctions on the Exchange if they are subject to a ''Block Only'' or ''Cancel and Block'' Automated Breach Action if they do not seek to include DMM Interest in such auction.

Finally, the Exchange believes that the proposed rule change does not unfairly discriminate among the Exchange's member organizations because use of the Pre-Trade Risk Controls is optional and is not a prerequisite for participation on the Exchange. In addition, because all orders on the Exchange would pass through the risk checks, there would be no difference in the latency experienced by member organizations who have opted to use the Pre-Trade Risk Controls

[14] 15 U.S.C. 78f(b).

[15] 15 U.S.C. 78f(b)(5).

versus those who have not opted to use them.

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. In fact, the Exchange believes that the proposal will have a positive effect on competition because, by providing Entering Firms and their Clearing Firms additional means to monitor and control risk, the proposed rule will increase confidence in the proper functioning of the markets. The Exchange believes the proposed Pre-Trade Risk Controls will assist Entering Firms and Clearing Firms in managing their financial exposure which, in turn, could enhance the integrity of trading on the securities markets and help to assure the stability of the financial system. As a result, the level of competition should increase as public confidence in the markets is solidified.

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 such longer period *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–NYSE–2020–17 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2020–17. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2020–17 and should be submitted on or before April 8, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–05561 Filed 3–17–20; 8:45 am]

BILLING CODE 8011–01–P

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 33815; 812–15074]

Conversus StepStone Private Markets and StepStone Conversus LLC; Notice of Application

March 12, 2020.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice.

Notice of an application under section 6(c) of the Investment Company Act of 1940 (the ''Act'') for an exemption from sections 18(a)(2), 18(c), and 18(i) of the Act, pursuant to sections 6(c) and 23(c) of the Act, granting an exemption from rule 23c–3 under the Act, and for an order pursuant to section 17(d) of the Act and rule 17d–1 under the Act.

SUMMARY OF APPLICATION: Applicants request an order to permit certain registered closed-end management investment companies to issue multiple classes of shares of beneficial interest (''Shares'') and to impose asset-based service and/or distribution fees and early withdrawal charges.

APPLICANTS: Conversus StepStone Private Markets (the ''Initial Fund'') and StepStone Conversus LLC (the ''Adviser'').

FILING DATES: The application was filed on October 16, 2019, and amended on January 14, 2020, and March 4, 2020.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on April 6, 2020, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, U.S. Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090; Applicants, 1422 S Tryon St., Suite 300, Charlotte, NC 28203.

FOR FURTHER INFORMATION CONTACT: Kieran G. Brown, Senior Counsel, at

(202) 551–6773 or Kaitlin C. Bottock, Branch Chief at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's website by searching for the file number, or an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Applicants' Representations

1. The Initial Fund is a Delaware statutory trust that is registered under the Act as a non-diversified, closed-end management investment company. The Initial Fund's investment objectives are to invest in a broad cross section of private markets assets that will enable the Initial Fund to, over time, achieve long-term capital appreciation and provide regular, current income through quarterly distributions.

2. The Adviser, a Delaware limited liability company, is registered as an investment adviser under the Investment Advisers Act of 1940. The Adviser serves as investment adviser to the Initial Fund.

3. The applicants seek an order to permit the Initial Fund to issue multiple classes of Shares, each having its own fee and expense structure, and to impose asset-based service and/or distribution fees and early withdrawal charges.

4. Applicants request that the order also apply to any other registered closed-end management investment company that conducts a continuous offering of its shares, existing now or in the future, for which the Adviser, its successors,[1] or any entity controlling, controlled by, or under common control with the Adviser, or its successors, acts as investment adviser, and which provides periodic liquidity with respect to its Shares through tender offers conducted in compliance with either rule 23c–3 under the Act or rule 13e–4 under the Securities Exchange Act of 1934 (the ''1934 Act'') (each such closed-end investment company, a ''Future Fund'' and, together with the Initial Fund, each, a ''Fund'' and collectively, the ''Funds'').[2]

5. The Initial Fund intends to issue a single class of Shares (the ''Initial Class Shares''). The Shares will be offered on a continuous basis at net asset value per share plus the applicable sales load. The Initial Fund, as a closed-end investment company, will not continuously redeem Shares as does an open-end management investment company. Shares of the Initial Fund will not be listed on any securities exchange and do not trade on an over-the-counter system. Applicants do not expect that any secondary market will ever develop for the Shares.

6. If the requested relief is granted, the Initial Fund intends to offer multiple classes of Shares, such as the Initial Class Shares, or any other classes. Because of the different distribution fees, shareholder services fees, and any other class expenses that may be attributable to the different classes, the net income attributable to, and any dividends payable on, each class of Shares may differ from each other from time to time.

7. Applicants state that, from time to time, the Board of a Fund may create additional classes of Shares, or may vary the characteristics of the Initial Class described in the application, including without limitation, in the following respects: (1) The amount of fees permitted by different distribution plans or different service fee arrangements; (2) voting rights with respect to a distribution plan of a class; (3) different class designations; (4) the impact of any class expenses directly attributable to a particular class of Shares allocated on a class basis as described in the application; (5) differences in any dividends and net asset values per Share resulting from differences in fees under a distribution plan or in class expenses; (6) any early withdrawal charge or other sales load structure; and (7) any exchange or conversion features, as permitted under the Act.

8. Applicants state that, in order to provide some liquidity to shareholders, the Initial Fund may from time to time offer to repurchase Shares at net asset value pursuant to written tenders by shareholders in accordance with rule 13e–4 under the 1934 Act (''Repurchases''). Repurchases of the Fund's Shares will be made at such times, in such amounts and on such terms as may be determined by the Fund's Board in its sole discretion. Any other investment company that intends to rely on the requested relief will provide periodic liquidity to shareholders in accordance with either rule 23c–3 under the Act or rule 13e–4 under the 1934 Act.

9. Applicants represent that any asset-based service and/or distribution fees of a Fund will comply with the provisions of Rule 2341 of the Rules of the Financial Industry Regulatory Authority (''FINRA Rule 2341'') as if that rule applied to the Fund.[3] Applicants also represent that each Fund will disclose in its prospectus the fees, expenses and other characteristics of each class of Shares offered for sale by the prospectus, as is required for open-end, multiple class funds under Form N–1A. As is required for open-end funds, each Fund will disclose its expenses in shareholder reports, and describe any arrangements that result in breakpoints in, or elimination of, sales loads in its prospectus.[4] In addition, applicants will comply with applicable enhanced fee disclosure requirements for fund of funds, including registered funds of hedge funds.[5]

10. Each Fund and its distributor (the ''Distributor'') will also comply with any requirements that may be adopted by the Commission or FINRA regarding disclosure at the point of sale and in transaction confirmations about the costs and conflicts of interest arising out of the distribution of open-end investment company shares, and regarding prospectus disclosure of sales loads and revenue sharing arrangements as if those requirements applied to the Fund and the Distributor. Each Fund or the Distributor will contractually require that any other distributor of the Fund's Shares comply with such requirements in connection with the distribution of Shares of the Fund.

11. Each Fund will allocate all expenses incurred by it among its various classes of Shares based on the net assets of the Fund attributable to each class, except that the net asset value and expenses of each class will reflect distribution fees, service fees, and any other incremental expenses of that class. Expenses of a Fund allocated to a particular class of the Fund's Shares

[1] A successor in interest is limited to an entity that results from a reorganization into another jurisdiction or a change in the type of business organization.

[2] The Initial Fund and any Future Fund relying on the requested relief will do so in a manner consistent with the terms and conditions of the application. Applicants represent that any person presently intending to rely on the requested relief is listed as an applicant.

[3] Any references to FINRA Rule 2341 include any successor or replacement rule that may be adopted by the Financial Industry Regulatory Authority (''FINRA'').

[4] *See* Shareholder Reports and Quarterly Portfolio Disclosure of Registered Management Investment Companies, Investment Company Act Release No. 26372 (Feb. 27, 2004) (adopting release) (requiring open-end investment companies to disclose fund expenses in shareholder reports); and Disclosure of Breakpoint Discounts by Mutual Funds, Investment Company Act Release No. 26464 (June 7, 2004) (adopting release) (requiring open-end investment companies to provide prospectus disclosure of certain sales load information).

[5] Fund of Funds Investments, Investment Company Act Rel. Nos. 26198 (Oct. 1, 2003) (proposing release) and 27399 (Jun. 20, 2006) (adopting release). See also rules 12d1–1, *et seq.* of the Act.

will be borne on a pro rata basis by each outstanding Share of that class. Applicants state that each Fund will comply with the provisions of rule 18f–3 under the Act as if it were an open-end investment company.

12. Applicants state that the Initial Fund does not intend to offer any exchange privilege or conversion feature, but any such privilege or feature introduced in the future by a Fund will comply with rule 11a–1, rule 11a–3, and rule 18f–3 as if the Fund were an open-end investment company.

13. Applicants state that the Initial Fund does not currently intend to impose an early withdrawal charge. However, in the future a Fund may impose an early withdrawal charge on shares submitted for repurchase that have been held less than a specified period. The Fund may waive the early withdrawal charge for certain categories of shareholders or transactions to be established from time to time. Applicants state that each Fund will apply the early withdrawal charge (and any waivers or scheduled variations of the early withdrawal charge) uniformly to all shareholders in a given class and consistently with the requirements of rule 22d–1 under the Act as if the Fund was an open-end investment company.

14. Each Fund operating as an interval fund pursuant to rule 23c–3 under the Act may offer its shareholders an exchange feature under which the shareholders of the Fund may, in connection with such Fund's periodic repurchase offers, exchange their Shares of the Fund for shares of the same class of (i) registered open-end investment companies or (ii) other registered closed-end investment companies that comply with rule 23c–3 under the Act and continuously offer their shares at net asset value, that are in the Fund's group of investment companies (collectively, the ''Other Funds''). Shares of a Fund operating pursuant to rule 23c–3 that are exchanged for shares of Other Funds will be included as part of the repurchase offer amount for such Fund as specified in rule 23c–3 under the Act. Any exchange option will comply with rule 11a–3 under the Act, as if the Fund were an open-end investment company subject to rule 11a–3. In complying with rule 11a–3 under the Act, each Fund will treat an early withdrawal charge as if it were a contingent deferred sales load.

15. Applicants state that the Initial Fund does not currently intend to impose a repurchase fee, but may do so in the future.[6] If a Fund charges a repurchase fee, Shares of the Fund will be subject to a repurchase fee at a rate of no greater than 2% of the shareholder's repurchase proceeds if the interval between the date of purchase of the Shares and the valuation date with respect to the repurchase of those Shares is less than one year. Repurchase fees, if charged, will equally apply to all classes of Shares of the Fund, consistent with section 18 of the Act and rule 18f–3 thereunder. To the extent a Fund determines to waive, impose scheduled variations of, or eliminate a repurchase fee, it will do so consistently with the requirements of rule 22d–1 under the Act as if the repurchase fee were a contingent deferred sales load and as if the Fund were a registered open-end investment company and the Fund's waiver of, scheduled variation in, or elimination of, the repurchase fee will apply uniformly to all shareholders of the Fund regardless of class.

Applicants' Legal Analysis

Multiple Classes of Shares

1. Section 18(a)(2)(A) and (B) makes it unlawful for a registered closed-end investment company to issue a senior security that is a stock unless (a) immediately after such issuance it will have an asset coverage of at least 200% and (b) provision is made to prohibit the declaration of any distribution, upon its common stock, or the purchase of any such common stock, unless in every such case such senior security has at the time of the declaration of any such distribution, or at the time of any such purchase, an asset coverage of at least 200% after deducting the amount of such distribution or purchase price, as the case may be. Applicants state that the creation of multiple classes of shares of the Funds may violate section 18(a)(2) because the Funds may not meet such requirements with respect to a class of shares that may be a senior security.

2. Section 18(c) of the Act provides, in relevant part, that a registered closed-end investment company may not issue or sell any senior security if, immediately thereafter, the company has outstanding more than one class of senior security. Applicants state that the creation of multiple classes of Shares of a Fund may be prohibited by section 18(c), as a class may have priority over another class as to payment of dividends because shareholders of different classes would pay different fees and expenses.

3. Section 18(i) of the Act provides that each share of stock issued by a registered management investment company will be a voting stock and have equal voting rights with every other outstanding voting stock. Applicants state that permitting multiple classes of Shares of a Fund may violate section 18(i) of the Act because each class would be entitled to exclusive voting rights with respect to matters solely related to that class.

4. Section 6(c) of the Act provides that the Commission may exempt any person, security or transaction or any class or classes of persons, securities or transactions from any provision of the Act, or from any rule or regulation under the Act, if and to the extent such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants request an exemption under section 6(c) from sections 18(a)(2), 18(c) and 18(i) to permit the Funds to issue multiple classes of Shares.

5. Applicants submit that the proposed allocation of expenses relating to distribution and voting rights among multiple classes is equitable and will not discriminate against any group or class of shareholders. Applicants submit that the proposed arrangements would permit each Fund to facilitate the distribution of its Shares and provide investors with a broader choice of shareholder options. Applicants assert that the proposed closed-end investment company multiple class structure does not raise the concerns underlying section 18 of the Act to any greater degree than open-end investment companies' multiple class structures that are permitted by rule 18f–3 under the Act. Applicants state that each Fund will comply with the provisions of rule 18f–3 as if it were an open-end investment company.

Early Withdrawal Charges

1. Section 23(c) of the Act provides, in relevant part, that no registered closed-end investment company shall purchase securities of which it is the issuer, except: (a) On a securities exchange or other open market; (b) pursuant to tenders, after reasonable opportunity to submit tenders given to all holders of securities of the class to be purchased; or (c) under other circumstances as the Commission may permit by rules and regulations or orders for the protection of investors.

2. Rule 23c–3 under the Act permits a registered closed-end investment company (an ''interval fund'') to make repurchase offers of between five and

[6] Unlike a distribution-related charge, the repurchase fee is payable to the Fund to compensate long-term shareholders for the expenses related to shorter-term investors, in light of the Fund's generally longer-term investment horizons and investment operations.

twenty-five percent of its outstanding shares at net asset value at periodic intervals pursuant to a fundamental policy of the interval fund. Rule 23c–3(b)(1) under the Act permits an interval fund to deduct from repurchase proceeds only a repurchase fee, not to exceed two percent of the proceeds, that is paid to the interval fund and is reasonably intended to compensate the fund for expenses directly related to the repurchase.

3. Section 23(c)(3) provides that the Commission may issue an order that would permit a closed-end investment company to repurchase its shares in circumstances in which the repurchase is made in a manner or on a basis that does not unfairly discriminate against any holders of the class or classes of securities to be purchased.

4. Applicants request relief under section 6(c), discussed above, and section 23(c)(3) from rule 23c–3 to the extent necessary for each Fund to impose early withdrawal charges on shares of the Fund submitted for repurchase that have been held for less than a specified period.

5. Applicants state that the early withdrawal charges they intend to impose are functionally similar to contingent deferred sales loads imposed by open-end investment companies under rule 6c–10 under the Act. Rule 6c–10 permits open-end investment companies to impose contingent deferred sales loads, subject to certain conditions. Applicants note that rule 6c–10 is grounded in policy considerations supporting the employment of contingent deferred sales loads where there are adequate safeguards for the investor and state that the same policy considerations support imposition of early withdrawal charges in the interval fund context. In addition, applicants state that early withdrawal charges may be necessary for the Fund's Distributor to recover distribution costs. Applicants represent that any early withdrawal charge imposed by a Fund will comply with rule 6c–10 under the Act as if the rule were applicable to closed-end investment companies. Each Fund will disclose early withdrawal charges in accordance with the requirements of Form N–1A concerning contingent deferred sales loads.

Asset-Based Service and/or Distribution Fees

1. Section 17(d) of the Act and rule 17d–1 under the Act prohibit an affiliated person of a registered investment company or an affiliated person of such person, acting as principal, from participating in or effecting any transaction in connection with any joint enterprise or joint arrangement in which the investment company participates unless the Commission issues an order permitting the transaction. In reviewing applications submitted under section 17(d) and rule 17d–1, the Commission considers whether the participation of the investment company in a joint enterprise or joint arrangement is consistent with the provisions, policies and purposes of the Act, and the extent to which the participation is on a basis different from or less advantageous than that of other participants.

2. Rule 17d–3 under the Act provides an exemption from section 17(d) and rule 17d–1 to permit open-end investment companies to enter into distribution arrangements pursuant to rule 12b–1 under the Act. Applicants request an order under section 17(d) and rule 17d–1 under the Act to permit the Fund to impose asset-based service and/or distribution fees. Applicants have agreed to comply with rules 12b–1 and 17d–3 as if those rules applied to closed-end investment companies, which they believe will resolve any concerns that might arise in connection with a Fund financing the distribution of its shares through asset-based service and/or distribution fees.

For the reasons stated above, applicants submit that the exemptions requested under section 6(c) are necessary and appropriate in the public interest and are consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants further submit that the relief requested pursuant to section 23(c)(3) will be consistent with the protection of investors and will insure that applicants do not unfairly discriminate against any holders of the class of securities to be purchased. Finally, applicants state that the Funds' imposition of asset-based service and/or distribution fees is consistent with the provisions, policies and purposes of the Act and does not involve participation on a basis different from or less advantageous than that of other participants.

Applicants' Condition

Applicants agree that any order granting the requested relief will be subject to the following condition:

Each Fund relying on the requested order will comply with the provisions of rules 6c–10, 12b–1, 17d–3, 18f–3, 22d–1 and, where applicable, 11a–3 under the Act, as amended from time to time or replaced, as if those rules applied to closed-end management investment companies, and will comply with FINRA Rule 2341, as amended from time to time, as if that rule applied to all closed-end management investment companies.

For the Commission, by the Division of Investment Management, under delegated authority.

J. Matthew DeLesDernier,

Assistant Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–88373; File No. SR–NYSE–2020–14]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Extend the Transition Period for Member Organizations To Transition to the Utilization of Ports That Connect to the Exchange Using Pillar Technology

March 12, 2020.

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 March 2, 2020, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its Price List to (1) extend the Transition Period for member organizations to transition to the utilization of ports that connect to the Exchange using Pillar technology; (2) shorten the Decommission Period from six to four months; (3) extend the effective date that the Exchange would prorate the monthly fee for ports activated on or after July 1, 2019; and (4) revise the fees charged for legacy port connections during the Decommission Period. The Exchange proposes to implement these changes to its Price List effective March 2, 2020. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

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 Statutory Basis for, the Proposed Rule Change

1. Purpose

Effective July 3, 2019, the Exchange introduced transition pricing designed to provide member organizations an extended transition period to connect to the Exchange using Pillar technology with no fee increase. Specifically, the Exchange (1) adopted a cap on monthly fees for the use of certain ports connecting to the Exchange for the billing months July 2019 through March 2020 (the ''Transition Period''); (2) adopted a Decommission Extension Fee applicable for the billing months April 2020 through September 2020 (the ''Decommission Period'') for legacy port connections; and (3) prorated the monthly fee for certain ports activated after July 1, 2019, effective April 1, 2020.[4]

The Exchange proposes to

- extend the end of the Transition Period from March 2020 to August 2020 for member organizations to transition to the utilization of ports that connect to the Exchange using Pillar technology;
- shorten the Decommission Period that begins once the transition period ends from six months (April 2020–September 2020) to four months (September–December 2020);
- extend the effective date that the Exchange would prorate the monthly fee for certain ports activated on or after July 1, 2019 from April 1, 2020 to September 1, 2020; and
- revise the fees charged for legacy port connections during the Decommission Period.

The purpose of this filing is to provide additional time for member organizations to transition from older to newer and more efficient Pillar technology. The Exchange is not proposing to adjust the amount of the port fees, which will remain at the current level for all market participants. The Exchange would continue to provide a cap on how much member organizations would be charged for ports during the proposed extra five months of the Transition Period so that they would not incur additional charges during the transition to Pillar communication protocols. Moreover, the Exchange proposes to shorten the period during which the few firms that do not transition during the proposed longer Transition Period would be charged fees to offset the Exchange's continuing costs of supporting legacy ports, and proposes to increase those fees to account for the overall longer time period that the Exchange would need to support legacy ports.

The Exchange proposes to implement these changes to its Price List effective March 2, 2020.

Competitive Environment

The Exchange operates in a highly competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.''[5]

As the Commission itself recognized, the market for trading services in NMS stocks has become ''more fragmented and competitive.''[6] Indeed, equity trading is currently dispersed across 13 exchanges,[7] 31 alternative trading systems,[8] and numerous broker-dealer internalizers and wholesalers. Based on publicly-available information, no single exchange has more than 20% of the market share of executed volume of equity trades (whether excluding or including auction volume).[9] 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 or reduce use of certain categories of products, including ports, in response to fee changes. Accordingly, the Exchange's fees, including port fees, are reasonably constrained by competitive alternatives and market participants can readily trade on competing venues if they deem pricing levels at those other venues to be more favorable.

The Exchange is proposing these changes in the context of a competitive environment in which market participants can and do shift order flow, or discontinue or reduce use of certain categories of products, in response to fee changes. Because ports are used by member organizations to trade electronically on the Exchange, fees associated with ports are subject to these same competitive forces. The Exchange believes that the proposal represents a reasonable attempt to provide member organizations with additional time to effect an orderly transition to upgraded technology without incurring additional costs. If a member organization is unable to complete this transition within the proposed longer period, the proposed pricing is designed to offset the Exchange's continuing costs of supporting legacy ports for a longer period of time.

Proposed Rule Change

Member organizations enter orders and order instructions, and receive information from the Exchange, by establishing a connection to a gateway that uses communication protocols that map to the order types and modifiers described in Exchange rules. These gateway connections, also known as logical port connections, are referred to as ''ports'' on the Exchange's Price List. Legacy ports connect with the Exchange via a Common Customer Gateway (known as ''CCG'') that accesses its equity trading systems (''Phase I ports''). Beginning July 1, 2019, the Exchange began to make available ports using Pillar gateways to its member organizations (''Phase II ports'').

Extension of the Date To Prorate Ports

The Exchange currently makes available ports that provide connectivity

[4] *See* Securities Exchange Act Release No. 86360 (July 11, 2019), 84 FR 34210 (SR–NYSE–2019–39).

[5] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37495, 37499 (June 29, 2005) (S7–10–04) (''Regulation NMS'').

[6] *See* Securities Exchange Act Release No. 51808, 84 FR 5202, 5253 (February 20, 2019) (File No. S7–05–18) (Transaction Fee Pilot for NMS Stocks Final Rule) (''Transaction Fee Pilot'').

[7] *See* Cboe Global Markets, U.S. Equities Market Volume Summary, available at *http://markets.cboe.com/us/equities/market_share/. See generally https://www.sec.gov/fast-answers/divisionsmarketregmrexchangesshtml.html.*

[8] *See* FINRA ATS Transparency Data, *available at https://otctransparency.finra.org/otctransparency/AtsIssueData.* A list of alternative trading systems registered with the Commission is *available at https://www.sec.gov/foia/docs/atslist.htm.*

[9] *See* Cboe Global Markets U.S. Equities Market Volume Summary, available at *http://markets.cboe.com/us/equities/market_share/.*

to the Exchange's trading systems (*i.e.,* ports for entry of orders and/or quotes (''order/quote entry ports'')) and charges $550 per port per month. Designated Market Makers (''DMMs'') are not charged for the first 12 ports per month that connect to the Exchange.[10] The Exchange also currently makes ports available for drop copies and charges $550 per port per month,[11] except that DMMs are not charged for drop copy ports that connect to the Exchange.

During the ongoing first phase of the Exchange's transition pricing, the fees charged for both order/quote entry and drop copy ports are, with certain exceptions, capped at—and thus not charged for more than—the total number of both order/quote entry and drop copy ports that the member organization has activated as of its June 2019 invoice.

Effective April 1, 2020, the Exchange will prorate fees for order/quote entry and drop copy ports activated after July 1, 2019, to the number of trading days that a port is eligible for production trading with the Exchange, including any scheduled early closing days.

The Exchange proposes to extend the effective date for the prorating of order/quote entry and drop copy ports to September 1, 2020 to coincide with the end of the proposed extended Transition Period in August 2020, discussed below.

Extension of the Transition Period

Currently, during the billing months of July 2019 through March 2020 (the ''Transition Period''), the total number of ports charged per member organization is capped at the total number of ports that the member organization activated as of the June 2019 invoice, which was the last full month prior to the introduction of the new gateways (the ''Transition Cap''). Transition Cap pricing is available until the earlier of (1) the end of the Transition Period, *i.e.,* March 2020, or (2) the billing month during which a member organization fully transitions to using only ports that communicate using Pillar phase II protocols. If during the Transition Period, a member organization increases the number of Phase I ports above the Transition Cap, those ports would be charged at the current rates for order/quote entry ports and drop copy ports. Finally, if during the Transition Period a member organization has a total number of ports below the Transition Cap, the Exchange would charge a member organization for their actual number of ports.

The Exchange proposes to extend the Transition Period by five months to August 2020. As proposed, the charge per port (order/quote entry and drop copy) would remain at $550 per port per month. DMMs would continue not to be charged for drop copy ports and for their first 12 order/quote entry ports per month that connect to the Exchange and then charged $550 per order/quote entry port that connects to the Exchange per month thereafter.

The purpose of Transition Period pricing is to cap port fees to allow member organizations additional time to implement technology changes necessary to connect to the Exchange using the Phase II ports without incurring additional Exchange fees. As of January 2020, only 42% of Phase I ports have been cancelled. Based on the Exchange's experience to date, the Exchange believes that an additional five months will be necessary to provide sufficient time for all member organizations, regardless of size, to be able to complete the necessary changes and transition fully to the Phase II ports.

Extension of the Decommission Period and New Decommission Extension Fee

Currently, member organizations that have not transitioned to Phase II ports and are still utilizing Phase I ports during the billing months of April 2020 through September 2020 (*i.e.,* the Decommission Period), would, in addition to the current port fees, be charged a Decommission Extension Fee of $500 per port per month, increasing by $500 per port for each month for any ports that communicate using Pillar phase I protocols. As per the Price List, ports using Pillar phase I protocols would no longer be available beginning October 1, 2020.

The Exchange proposes that the Decommission Period would begin in September 2020, after the end of the proposed longer Transition Period, and shortened to four months. As proposed, the Decommission Period would commence in September 2020 and end in December 2020. As a result, the Price List would also be amended to provide that ports using Pillar phase I protocols would no longer be available beginning January 1, 2021. The Exchange further proposes to increase the Decommission Extension Fee to $1,000 per port per month and increasing by $1,000 per port for each month for any ports that communicate using Pillar phase I protocols.

For example, in January 2020, Firm A has 10 Phase I ports and a Transition Cap of 10 ports. By September 2020, the first month of the proposed Decommission Period, Firm A still has two Phase I ports. In this scenario, Firm A would be charged the standard port rate for two Phase I ports plus $1,000 per port for the Decommission Extension Fee.

If Firm A has the same two Phase I ports in October 2020, Firm A would be charged the standard port rate for the two Phase I ports plus $2,000 per port for the Decommission Extension Fee.

If Firm A retains the two Phase I ports until December 2020, the final month of the proposed enlarged Decommission Period, Firm A would be charged the standard port rate for the two Phase I ports plus $4,000 per port for the Decommission Extension Fee.

As noted above, the Exchange believes that a longer Transition Period would provide sufficient time for member organizations to fully transition to Phase II ports and eliminate their use of Phase I ports. To the extent that member organizations do not complete the transition during the Transition Period, the Exchange will offer member organizations the ability to choose to continue using Phase I ports until December 2020. To cover the costs associated with maintaining and supporting both Phase I ports and Phase II ports beyond the longer Transition Period, and to provide an added incentive for member organizations to migrate to Phase II ports before the end of the Transition Period, the Exchange proposes to increase the costs for the expected very small number of member organizations that would need longer to transition than the 14-month Transition Period. Specifically, to support the continued availability of the Phase I ports, the Exchange would have to maintain additional hardware and devote technology resources to maintain and operate those ports, which is a cost to the Exchange. While these costs cannot be specifically quantified and it is unknown how many (if any) member organizations would need to continue to access the Exchange using Phase I ports after the Transition Period, the Exchange believes that the proposed increased Decommission Extension Fee would, in part, cover the costs associated with continuing to support the Phase I port infrastructure for use by a dwindling number of member organizations. The Exchange believes that the proposed additional five months will provide more than sufficient time for the transition and that fewer member organizations will choose to pay the proposed Decommission Fee because they do not transition within the extended Transition Period.

[10] DMMs completed the transition to Phase II ports last year.

[11] Only one fee per drop copy port applies, even if receiving drop copies from multiple order/quote entry ports.

The proposed changes are not otherwise intended to address any other issues, and the Exchange is not aware of any problems that member organizations would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[12] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[13] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Proposed Changes Are Reasonable

The Exchange operates in a highly competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [14]

As the Commission itself recognized, the market for trading services in NMS stocks has become ''more fragmented and competitive.'' [15] Indeed, equity trading is currently dispersed across 13 exchanges,[16] 31 alternative trading systems,[17] and numerous broker-dealer internalizers and wholesalers. Based on publicly-available information, no single exchange has more than 20% of the market share of executed volume of equity trades (whether excluding or including auction volume).[18] 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 or reduce use of certain categories of products, including ports, in response to fee changes. Accordingly, the Exchange's fees, including port fees, are reasonably constrained by competitive alternatives and market participants can readily trade on competing venues if they deem pricing levels at those other venues to be more favorable.

If a particular exchange charges excessive fees for connectivity, impacted members and non-members may opt to terminate their connectivity arrangements with that exchange, and adopt a possible range of alternative strategies, including routing to the applicable exchange through another participant or market center or taking that exchange's data indirectly. Accordingly, if the Exchange charges excessive fees, it would stand to lose not only connectivity revenues but also revenues associated with the execution of orders routed to it, and, to the extent applicable, market data revenues. The Exchange believes that this competitive dynamic imposes powerful restraints on the ability of any exchange to charge unreasonable fees for connectivity.

Given this competitive environment, the proposal represents a fair and reasonable attempt to provide member organizations with additional time to make an orderly transition to upgraded technology without increasing their costs. As noted, more than half of legacy ports have not been cancelled. If a member organization is unable to complete this transition within the additional five months of the extended Transition Period, the pricing is designed so that only those few member organizations that may not transition within that time period would pay for the Exchange to continue to support their Phase I ports. Additionally, the Exchange believes that the revised Decommission Extension Fee for member organizations that choose to continue to connect to the Exchange through the use of Phase I ports following the end of the Transition Period is reasonable because the Exchange would continue to incur ongoing costs in maintaining Phase I ports for a longer period of time.

The Proposal Is an Equitable Allocation of Fees

The Exchange believes its proposal equitably allocates its fees among its market participants. The Exchange is not proposing to adjust the amount of the port fees, which will remain at the current level for all market participants. Rather, the proposal would revise the Decommission Extension Fee for those few member organizations that choose not to transition to Phase II ports during the extended Transition Period.

The Exchange believes that the proposal constitutes an equitable allocation of fees because all similarly situated member organizations and other market participants eligible for the Decommission Extension Fee would be charged the same rates. Specifically, the proposed revised Decommission Extension Fee would apply equally to all member organizations that choose to connect to the Exchange through the use of Phase I ports during the Decommission Period. Moreover, as noted above, the Exchange proposes a longer transition period which the Exchange expects should be more than sufficient for all member organizations, regardless of size, to transition to Phase II ports before the proposed revised Decommission Fee goes into effect.

The proposal to pro-rate port fees beginning September 1, 2020, is also an equitable allocation of fees since it would apply equally to all member organizations that connect to the Exchange, who would equally receive the benefit of being charged only for the connectivity utilized during any trading month beginning in September 1, 2020. As noted above, to the extent a member organization continues to use ports activated before July 1, 2019 to connect to the Exchange during the new September 1, 2020 date and any subsequent months, the Exchange believes it is fair and equitable to continue to charge flat fees for such ports until such time that connection to the Exchange through the use of Phase I ports is no longer available beginning January 1, 2021.

The Proposal Is Not Unfairly Discriminatory

The Exchange believes that the proposal is not unfairly discriminatory. In the prevailing competitive environment, member organizations are free to disfavor the Exchange's pricing if they believe that alternatives offer them better value, and are free to discontinue to connect to the Exchange through its ports. As noted, the Exchange is offering upgraded connections in an effort to keep pace with changes in the industry and evolving customer needs as new technologies emerge and products continue to develop and change.

The proposal neither targets nor will it have a disparate impact on any particular category of market participant. The Exchange believes that the proposal does not permit unfair discrimination because the proposal would be applied to all similarly

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(4) & (5).

[14] *See* Regulation NMS, 70 FR at 37499.

[15] *See* Transaction Fee Pilot, 84 FR at 5253.

[16] *See* Cboe Global Markets, U.S. Equities Market Volume, available at *http://markets.cboe.com/us/equities/market_share/. See generally https://www.sec.gov/fast-answers/divisionsmarketregmrexchangesshtml.html.*

[17] *See* FINRA ATS Transparency Data, *available at https://otctransparency.finra.org/otctransparency/AtsIssueData.* A list of alternative trading systems registered with the Commission is *available at https://www.sec.gov/foia/docs/atslist.htm.*

[18] *See* Cboe Global Markets U.S. Equities Market Volume Summary, available at *http://markets.cboe.com/us/equities/market_share/.*

situated member organizations and other market participants would be charged the same rates.

The Exchange believes that the proposal does not permit unfair discrimination because the Exchange will be making available both the Phase I and Phase II ports available to all member organizations during the extended Transition Period on an equal basis. Accordingly, no member organization already operating on the Exchange would be disadvantaged by this allocation of fees. For the same reasons, the Exchange believes that the proposal would not permit unfair discrimination between member organizations.

Similarly, the proposal does not permit unfair discrimination between member organizations because the proposed revised Decommission Extension Fee would apply equally to all member organizations that choose to connect to the Exchange through the use of such ports during the proposed Decommission Period. If a member organizations becomes subject to the Decommission Fee, it would only be because such firm chose not to complete its transition to the Phase II ports by the end of the longer Transition Period. While the Exchange cannot predict with certainty whether any firms would be subject to the Decommission Fee, and if so, which ones, the Exchange anticipates that it would be a limited set of member organizations that would incur such fees. Moreover, the Exchange believes that increasing the Decommission Extension Fee for each month for ports that communicate using Pillar phase I protocols once the new Decommission Period begins would also apply equally to all member organizations that continue to choose to connect to the Exchange utilizing legacy ports.

The Exchange believes that the proposal to pro-rate port fees does not permit unfair discrimination because it would apply equally to all member organizations that connect to the Exchange, who would equally receive the benefit of being charged only for the connectivity utilized during any trading month beginning September 1, 2020. As noted, to the extent a member organization continues to use ports activated before July 1, 2019 to connect to the Exchange during September 1, 2020 and any subsequent months, the Exchange believes it is fair, equitable and not unfairly discriminatory to continue to charge flat fees for such ports until such time that connection to the Exchange through the use of old ports is no longer available beginning January 1, 2021.

Finally, the Exchange believes that it is subject to significant competitive forces, as described below in the Exchange's statement regarding the burden on competition.

For the foregoing reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[19] the Exchange believes that the proposed rule change would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, as discussed above, the Exchange believes that the proposed changes would provide additional time for member organizations to transition from older to newer and more efficient Pillar technology with no fee increase and offset the Exchange's continuing costs of supporting the Phase I ports for the few firms that do not transition to the new ports during the longer transition period without any change to the fees currently charged by the Exchange for the use of ports to connect to the Exchange's trading systems.

Intramarket Competition. The Exchange does not believe the proposed rule change would impose any burden on intramarket competition that is not necessary or appropriate because it would apply to all member organizations equally that connect to the Exchange. All member organizations, regardless of size, will be eligible for the transition pricing through the extended Transition Period ending August 2020 and will be eligible to connect via either Phase I or Phase II ports during this period. In addition, all member organizations will be subject to the proposed Decommission Fee on an equal basis if they do complete the transition to Phase II ports by the end of the new August 2020 date. As noted, the Exchange anticipates that a low percentage of member organizations would be subject to the proposed Decommission Fee, and the firms likely to be subject to such fee would be larger firms that could more easily absorb the cost of that fee. The Exchange further believes that by extending the Transition Period and providing six months' notice of the revised Decommission Fee, all member organizations have an equal opportunity to timely transition to Phase II ports before the new Decommission Fee would take effect.

Intermarket Competition. The Exchange does not believe the proposed rule change would impose any burden on intermarket competition that is not necessary or appropriate because the Exchange operates in a highly competitive market in which market participants can readily choose to send their orders to other exchange and off-exchange venues if they deem fee levels at those other venues to be more favorable. The Exchange believes that fees for connectivity are constrained by the robust competition for order flow among exchanges and non-exchange markets.

As noted, the no single exchange has more than 20% of the market share of executed volume of equity trades (whether excluding or including auction volume).[20] 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 or reduce use of certain categories of products, including ports, in response to fee changes. Accordingly, the Exchange's fees, including port fees, are reasonably constrained by competitive alternatives and market participants can readily trade on competing venues if they deem pricing levels at those other venues to be more favorable.

The Exchange is proposing these changes in the context of a competitive environment in which market participants can and do shift order flow, or discontinue or reduce use of certain categories of products, in response to fee changes. Because ports are used by member organizations to trade electronically on the Exchange, fees associated with ports are subject to these same competitive forces. The Exchange therefore believes that the proposal would not impose an undue burden on intermarket competition because the purpose of this filing is not to change the rates charged for ports but rather to provide member organizations with more time to effect an orderly transition to upgraded technology without needing to incur any additional costs. If a member organization is unable to complete this transition within the proposed longer period, the pricing is designed to offset the Exchange's continuing costs of supporting legacy ports for a shorter period of time.

[19] 15 U.S.C. 78f(b)(8).

[20] *See* Cboe Global Markets U.S. Equities Market Volume Summary, available at *http://markets.cboe.com/us/equities/market_share/*.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A) [21] of the Act and subparagraph (f)(2) of Rule 19b–4 [22] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [23] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSE–2020–14 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street, NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2020–14. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2020–14 and should be submitted on or before April 8, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[24]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–05559 Filed 3–17–20; 8:45 am]

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[21] 15 U.S.C. 78s(b)(3)(A).

[22] 17 CFR 240.19b–4(f)(2).

[23] 15 U.S.C. 78s(b)(2)(B).

[24] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–88362; File No. SR–NYSE–2020–13]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing of Proposed Rule Change Amending Rule 7.31 (Orders and Modifiers) Relating to How Orders are Repriced and Make Related Changes to Rules 7.35, 7.36, and 7.38

March 12, 2020.

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 February 28, 2020, New York Stock Exchange LLC (''NYSE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 7.31 (Orders and Modifiers) relating to how orders are repriced and make related changes to Rules 7.35, 7.36, and 7.38. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 7.31 (Orders and Modifiers) relating to how orders are repriced and make related changes to Rules 7.35, 7.36, and 7.38.

Background

Currently, if an Away Market updates its PBBO and crosses not only the Exchange's BBO, but also displayed orders in the Exchange Book not represented in the BBO, *i.e.,* depth-of-book orders, and then the Exchange's BBO cancels or trades, the Exchange will not disseminate its next-best priced displayed order as its new BBO to the securities information processor (''SIP'').[3] Instead, the Exchange reprices

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The term ''Away Market'' is defined in Rule 1.1(b) to mean ''any exchange, alternative trading system (''ATS'') or other broker-dealer (1) with which the Exchange maintains an electronic linkage and (2) that provides instantaneous responses to orders routed from the Exchange.'' The term ''BBO'' is defined in Rule 1.1(c) to mean the best bid or offer on the Exchange, and the term ''BB'' means the best bid on the Exchange, and the term ''BO'' means the best offer on the Exchange. The term ''PBB'' is

such order before it is disseminated to the SIP.[4]

For example, if the Exchange's BB is $10.05 and on the Exchange Book, there is an order to buy 100 shares ranked Priority 2—Display Orders at $10.04 (''Order A''), Order A is displayed in the Exchange's proprietary depth-of-book market data at that $10.04 price but is not disseminated to the SIP.[5] If next, an Away Market publishes a PBO of $10.03, the Exchange's BB of $10.05 will stand its ground. However, if that $10.05 BB trades, cancels, or routes, the Exchange will not disseminate Order A to the SIP as the new BB at $10.04. Instead, as provided for in Rule 7.31(a)(2)(C), Order A will be assigned a display price of $10.02 and a working price of $10.03, which is equal to the Away Market PBO, and will be disseminated to the SIP as the Exchange's BB at $10.02. Order A will be repriced to $10.04 once the Away Market PBBO no longer locks or crosses the Exchange BBO. Each time Order A is repriced, including back to its original price, it is assigned a new working time.[6] The Exchange also applies this repricing functionality to D Orders, Primary Pegged Orders, and following an auction.[7]

The Exchange believes that no other exchange reprices resting depth orders in this manner. The Exchange understands that in the same scenario on other exchanges, ''Order A'' would stand its ground and be disseminated to the SIP as their new BBO at $10.04, even if that price would cross the Away Market PBO of $10.03. The rules of other exchanges vary regarding how much detail is used to describe circumstances when displayed orders stand their ground, and none explicitly address the specific scenario described above, *i.e.,* when a resting, displayed, depth-of-book order is crossed by an Away Market quotation and then becomes the best-priced order on that exchange. For example:

- The Nasdaq Stock Market LLC (''Nasdaq'') Rule 4756(c)(2) provides that Nasdaq transmits for display to the appropriate network processor its best-priced orders. That Rule specifies exceptions of which orders are not transmitted to the SIP, *i.e.,* the reserve size of orders, the discretionary portion of Discretionary Orders, and Non-Displayed Orders. This rule is silent as to whether resting, displayed, depth-of-book orders that have been locked or crossed by another market center and then become the best-ranked orders on Nasdaq are transmitted to the SIP at their original price. Separately, Nasdaq rules provide that certain previously-displayed orders stand their ground. For example, pursuant to Nasdaq Rules 4702(b)(1)(B) and 4702(b)(2)(B), resting ''Price to Comply Orders'' and ''Price to Display Orders'' entered via RASH, QIX, or FIX will stand their ground if locked or crossed by another market center. But these rules discuss top-of-book displayed orders that are crossed, not depth-of-book orders.
- CBOE BZX Exchange, Inc. (''BZX'') Rule 11.12(b) (Priority of Orders) provides that the best-ranked order(s) to buy and the best-ranked order(s) to sell that are displayable in the BZX Book and the aggregated displayed size of such orders associated with such prices shall be collected and made available to quotation vendors for dissemination pursuant to the requirements of Rule 602 of Regulation NMS. This rule is silent as to whether resting, displayed, depth-of-book orders that have been locked or crossed by another market center and then become the best-ranked orders on BZX are transmitted to the SIP at their original price. BZX Rule 11.13(a)(2)(C) (Order Execution and Routing) discusses how orders execute on BZX when the PBBO is crossed, and how that exchange processes incoming orders during a crossed market. But that rule does not address the scenario described above regarding resting, displayed, depth-of-book orders and whether they would be made available to quotation vendors for dissemination at their original price, even when the PBBO is crossed. Under Rule 11.13(b)(4), BZX further provides for optional ''Re-Route Instructions'' pursuant to which if a routable order has been locked or crossed by another market, the routable order on the BZX book would be routed to that other market. However, these are optional instructions, which implies that in the absence of one of these instructions, if a routable order on BZX is locked or crossed by another market, such order stands its ground.
- Investors Exchange LLC (''IEX'') Rule 11.240(c)(1) provides that IEX disseminates the aggregate of its best-ranked displayable orders to quotation vendors for dissemination to the SIPs. IEX Rules 11.190(h)(3)(A)(i) and (h)(3)(B)(i) further provide that resting orders that are displayed at a price that later becomes locked or crossed, and were originally displayed in compliance with rules and regulations of IEX, will maintain their displayed price and quantity.[8] While these rules do not distinguish between displayed orders at the top of the IEX book and depth-of-book displayed orders, these rules appear consistent with the Exchange's proposed change to provide that resting, displayed, depth-of-book orders would stand their ground and are eligible to be disseminated to the SIP as the BBO at their original displayed price.
- Long-Term Stock Exchange (''LTSE'') Rule 11.240(c)(1) provides that LTSE disseminates the aggregate of its best-ranked displayable orders to quotation vendors for dissemination to the SIPs.[9] LTSE Rules 11.190(g)(3)(A)(i) and (g)(3)(B)(i) further provide that resting orders that are displayed at a price that later becomes locked or crossed, and were originally displayed in compliance with rules and regulations of LTSE, will maintain their displayed price and quantity.[10] While these rules do not distinguish between displayed orders at the top of the LTSE book and at depth, these rules appear consistent with the Exchange's proposed change to provide that resting, displayed, depth-of-book orders would stand their ground and are eligible to be disseminated to the SIP as the BBO at their original displayed price.
- MEMX LLC (''MEMX'') has filed a Form 1 application for registration as a national securities exchange pursuant to

defined in Rule 1.1(q) to mean the highest Protected Bid, the term ''PBO'' means the lowest Protected Offer, and ''PBBO'' means the Best Protected Bid and Best Protected Offer. The terms ''Protected Bid'' and ''Protected Offer'' are defined in Rule 1.1(t). The term ''Exchange Book'' is defined in Rule 1.1(k) to mean the Exchange's electronic file of orders, which contains all orders entered on the Exchange.

[4] *See* Rule 7.31(a)(2)(C), which provides that ''[i]If a BB (BO) that is locked or crossed by an Away Market PBO (PBB) is cancelled, executed or routed and the next best-priced resting Limit Order(s) on the Exchange Book that would become the new BB (BO) would have a display price that would lock or cross the PBO (PBB), such Limit Order(s) to buy (sell) will be assigned a display price one MPV below (above) the PBO (PBB) and a working price equal to the PBO (PBB). When the PBO (PBB) is updated, the Limit Order(s) to buy (sell) will be repriced consistent with the original terms of the order. If a Day ISO to buy (sell) arrives before the PBO (PBB) is updated, such repriced Limit Order(s) to buy (sell) will be repriced to the lower (higher) of the display price of the Day ISO or the original price of the Limit Order(s).''

[5] *See* Rule 7.36(b)(3) (describing which orders are collected and made available to quotation vendors for dissemination pursuant to the requirements of Rule 602 under Regulation NMS under the Act).

[6] *See* Rule 7.36(f)(2) (an order is assigned a new working time any time its working price changes).

[7] *See* Rules 7.31(d)(4)(B)(i), 7.31(h)(2)(B), and 7.35(f)(3)(A)(iii).

[8] *See also* Supplementary Material .02 to Rule 11.190(h) (providing that ''[o]rders displayed on the Exchange which were displayed at a price compliant with Regulation NMS are generally permitted to maintain their displayed price in the event an away trading center locks or crosses the price of the IEX displayed order.'')

[9] LTSE has been approved as a registered exchange but is not yet operational.

[10] *See also* Supplementary Material .02 to LTSE Rule 11.190(g).

Section 6 of the Act.[11] Proposed MEMX Rule 11.9(b) provides that the best-ranked order(s) to buy and the best-ranked order(s) to sell that are displayable in the MEMX Book and the aggregate displayed size of such orders associated with such prices shall be collected and made available to the SIP.[12] MEMX claims that its proposed MEMX Rule 11.6(j)(1)(A)(ii), which provides that ''[f]ollowing the initial ranking and display or an order subject to the Display-Price Sliding instruction, an order will only be re-ranked and re-displayed to the extent it achieves a more aggressive price, provided, however, that the Exchange will re-rank an order at the same price as the displayed price in the event such orders' displayed price would be a Locking or Crossing Quotation'' makes clear that an order displayed by MEMX would not be re-priced to a less aggressive price if another market locked or crossed an order displayed by MEMX.[13] The Exchange understands this response to mean that MEMX would not re-price displayed orders that were at depth that would become the MEMX best bid or offer.

The Exchange proposes to amend its rules to conform how it reprices orders in this scenario to how other exchanges function. The Exchange believes that because such orders did not lock or cross an Away Market PBBO when they were entered on the Exchange and displayed to the Exchange's proprietary market data, such resting orders have priority at the price at which they were originally displayed.[14] In other words, such resting orders did not cause a locked or crossed market condition.

The Exchange further believes that providing priority to such resting orders on the Exchange Book (*e.g.,* disseminating ''Order A'' as a BB at $10.04 in the above-described scenario) would be consistent with Rule 610(d) under the Act (''Rule 610(d)'').[15] Rule 610(d) provides that ''[e]ach national securities exchange . . . shall establish, maintain, and enforce written rules that . . . are reasonably designed to assure the reconciliation of locked quotations in an NMS stock.'' The proposed rule change is consistent with this requirement because in the scenario described above, the Away Market has published a PBO that crosses not only the Exchange's BB, but also other orders that have already been entered on the Exchange and displayed on the Exchange's proprietary market data. Even though such depth-of-book orders have not yet been disseminated to the SIP as part of the Exchange's BBO, those resting orders pre-exist the Away Market quote that crossed them. Therefore, disseminating any pre-existing, displayed orders to the SIP as the new BB at their original price would be consistent with Rule 610(d) because it was the Away Market that crossed previously-displayed orders.

Proposed Rule Change

To effect this proposed rule change, the Exchange proposes to delete Rule 7.31(a)(2)(C) in its entirety. The Exchange also proposes to delete references to this Rule and describe how the Exchange would process orders, as follows.

First, the Exchange proposes several rule changes to specify that previously-displayed orders at any price stand their ground and remain eligible to be quoted or traded at their last-displayed price, even if locked or crossed by an Away Market. The Exchange proposes to specify this principal generally for all displayed orders by amending Rule 7.36(b) to add new subparagraph (4) that would provide that if an Away Market locks or crosses the BBO, the Exchange would not change the display price of any Limit Order ranked Priority 2—Display Orders[16] and any such orders would be eligible to be disseminated as the Exchange's BBO.[17] This proposed rule text both (1) provides specificity that all resting, top-of-book displayed orders stand their ground, which is current functionality,[18] and (2) describes new functionality for previously displayed depth-of-book orders, which would now stand their ground instead of being repriced if they become the Exchange's BBO.

Because such resting orders would no longer be repriced if locked or crossed by an Away Market, such orders would not need to be assigned new working times and would therefore retain priority at their original price. In addition, for market participants that read the Exchange's proprietary market data and are aware of displayed, depth-of-book orders, this proposed change provides greater certainty regarding the price at which a liquidity-taking order would execute on the Exchange.

This proposed rule text therefore promotes transparency and clarity in Exchange rules that all resting, displayed orders, including depth-of-book orders, would stand their ground if locked or crossed by an Away Market. Proposed Rule 7.36(b)(4) is based in part on IEX Rules 11.190(h)(3)(A)(i) and (h)(3)(B)(i) and LTSE Rules 11.190(g)(3)(A)(i) and (g)(3)(B)(i), described above, and is consistent with proposed MEMX Rule 11.6(j)(1)(A)(ii).

The Exchange proposes related changes to remove references to Rule 7.31(a)(2)(C) in connection with D Orders and Primary Pegged Orders and replace that rule text with proposed new functionality that such orders would stand their ground at their last-displayed price. As described above, if the PBBO becomes locked or crossed, displayed orders on the Exchange would stand their ground. The Exchange proposes that in such scenario, resting D Orders and Primary Pegged Orders, which are dynamically pegged to the PBBO, would similarly stand their ground. As further proposed, if the PBBO becomes locked or crossed, resting D Orders and Primary Pegged Orders would wait for a PBBO that is not locked or crossed before the display and working price of such orders are adjusted. While the market is locked or crossed, such orders would remain eligible to trade at their current working price.

To effect these changes, the Exchange proposes to amend Rule 7.31(d)(4)(B)(i) relating to D Orders by deleting the

[11] *See* Securities Exchange Act Release No. 87436 (October 31, 2019), 84 FR 59854 (November 6, 2019) (File No. 1–237). Although MEMX has not yet been approved as an exchange, the Exchange believes that its proposed rules are relevant to this discussion as MEMX expects to be operational in 2020, subject to approval of its Form 1 application.

[12] The proposed rule is silent regarding whether and how displayed odd-lot orders at more than one price point on MEMX would be aggregated to be displayed to the SIP. This ambiguity impacts other market participants' ability to calculate MEMX's protected best bid or offer in the same manner as MEMX.

[13] *See* Letter from Anders Franzon, General Counsel, MEMX, to Ms. Vanessa Countryman, Secretary, Securities and Exchange Commission, dated February 11, 2020, available here: *https://www.sec.gov/comments/10-237/10237-6795399-208386.pdf.*

[14] If the PBBO is locked or crossed at the time of an order's arrival, such arriving orders would be either routed, cancelled, or repriced, as provided for in Rule 7.37(c) (for routable orders) or Rule 7.31(e) (for non-routable orders). This proposed rule change is applicable only to resting orders.

[15] 17 CFR 242.610(d).

[16] As set forth in Rule 7.36(c), all non-marketable orders are ranked and maintained in the Exchange Book in the following manner: (1) Price; (2) priority category; (3) time; and (4) ranking restrictions applicable to an order or modifier condition. Under Rule 7.36(e)(2), ''Priority 2—Display Orders'' are non-marketable Limit Orders with a displayed working price. Limit Orders that are ranked Priority 2—Display Orders can be top of book or at depth.

[17] As set forth in Rule 7.36(b)(1), the Exchange considers an order to be ''displayed'' when it has been disseminated via a market data feed. Because all orders ranked Priority 2—Display Orders, regardless of price, are displayed via proprietary data feeds, such orders are all ''displayed'' for purposes of Exchange rules.

[18] Current Rule 7.31(e)(1)(A)(iii) specifies that Non-Routable Limit Orders stand their ground when crossed by an Away Market PBBO.

current text [19] and replacing it with the following: ''[i]f after arrival, the PBBO becomes locked or crossed, a D Order will wait for a PBBO that is not locked or crossed before the display and working price is adjusted and remains eligible to trade at its current working price.''

The Exchange also proposes to amend Rule 7.31(h)(2)(B) relating to Primary Pegged Orders by deleting the last clause of that Rule [20] and amend the last sentence of that paragraph as follows (new text underlined, proposed text for deletion in brackets): ''If after arrival, the PBBO becomes locked or crossed, the Primary Pegged Order will wait for a PBBO that is not locked or crossed before the *display and* working price [is]*are* adjusted[, but]*and* remains eligible to trade at its current working price.''

Second, the Exchange proposes to specify how the Exchange would process orders following either a UTP Regulatory Halt in a UTP Security or an Auction.[21] Because continuous trading did not precede either of these scenarios, the Exchange does not have a displayed quote eligible to stand its ground. Accordingly, to prevent publishing a quote that would lock or cross an Away Market, the Exchange proposes that before the Exchange publishes a quote following either of these scenarios, orders that are marketable against a protected quotation on an Away Market would be either routed (if routable) or cancelled (if non-routable).

The second clause of proposed new Rule 7.36(b)(4) would address how the Exchange would process orders before resuming trading and publishing a quote in a UTP Security following a UTP Regulatory Halt. This proposed rule text would be an exception to the first half of the rule text, described above, that previously-displayed orders stand their ground. The Exchange proposes this exception because during a UTP Regulatory Halt, there is no continuous trading and the Exchange ''zeroes'' out its quote, meaning the Exchange removes its BBO from the SIP. However, during a UTP Regulatory Halt, the Exchange may still have orders on its book. Specifically, as set forth in Rule 7.18(b), during a UTP Regulatory Halt, the Exchange cancels resting non-displayed orders and maintains all other resting orders in the Exchange Book at their last working price and display price. The Exchange does not accept new orders during such a halt. As provided for in Rule 7.18(a), the Exchange does not resume trading, including publishing a quote, in such security until it receives notification from the UTP Listing Market that the halt or suspension is no longer in effect and it has received the first Price Band in that security. The Exchange proposes that once it is eligible to resume trading, previously-displayed Limit Orders, *i.e.,* the orders entered before the UTP Regulatory Halt, would be routed (if routable) or cancelled (if non-routable) if such orders would be marketable against protected quotations on Away Markets.

For example, if before a UTP Regulatory Halt in XYZ security, the Exchange's BBO was $10.10 (100 shares) × $10.12 (100 shares), and before the Exchange resumes trading following that UTP Regulatory Halt, the first PBBO is $10.08 (100 shares) × $10.09 (100 shares), because the Exchange's former best bid of $10.10 is marketable against the new $10.09 PBO, the Exchange would either route that order (if routable) or cancel it (if non-routable). The Exchange would publish the former $10.12 because it is not marketable against an Away Market quotation.

To specify how orders would be processed before publishing a quote when transitioning to continuous trading following an Auction, the Exchange proposes to amend Rule 7.35(f)(3)(A). Currently, before publishing a quote following an Auction: (i) Reserve interest that replenishes the display quantity of a routable Reserve Order will route, if marketable against protected quotations on Away Markets; (ii) orders that are marketable against other orders in the Exchange Book and that would not trade through a protected quotation will trade; and (iii) the display price of all other orders that are marketable against a protected quotation on an Away Market will be adjusted consistent with Rule 7.31(a)(2)(C).

Because the Exchange will no longer be adjusting the price of orders as provided for in Rule 7.31(a)(2)(C), the Exchange proposes that, generally, to prevent publishing a quote that would lock or cross an Away Market PBBO, following an Auction, if orders are marketable against protected quotations on Away Markets, routable orders would route and non-routable orders would cancel. To effect this change, the Exchange proposes to amend Rule 7.35(f)(3)(A) to provide that, before publishing a quote, the Exchange would process orders as follows:

- Orders eligible to route (excluding D Orders that are routable) that are marketable against protected quotations on Away Markets would route based on the ranking of such orders as set forth in Rule 7.36(c) (proposed Rule 7.35(f)(3)(A)(i)). With this proposed change, routable orders at potentially multiple price points would be routed to protected quotations on Away Markets before any other action is taken.
- After routing eligible orders, orders not eligible to route (excluding Primary Pegged Orders, D Orders, and during a Short Sale Price Test, sell short orders) that are marketable against protected quotations on Away Markets would cancel (proposed Rule 7.35(f)(3)(A)(ii)). The Exchange does not propose to route or cancel Primary Pegged Orders, D Orders, or, during a Short Sale Price Test, sell short orders, because such orders, by their terms, are eligible to be repriced.
- Once there are no more unexecuted orders marketable against protected quotations on Away Markets (because they have either been routed or cancelled), orders that are marketable against other orders in the Exchange Book would trade (proposed Rule 7.35(f)(3)(A)(iii)). With this proposed step, remaining orders on the Exchange book that could trade would trade.
- The display quantity of Reserve Orders would be replenished as provided for in Rule 7.31(d)(1) (proposed Rule 7.35(f)(3)(A)(iv)).
- Primary Pegged Orders and D Orders would be assigned a display price and working price as provided for in Rule 7.31, provided that such orders would cancel if the PBBO is locked or crossed or there is no PBB (PBO) against which to peg (proposed Rule 7.35(f)(3)(A)(v)). Because these orders reprice on arrival, the Exchange proposes to process previously-entered Primary Pegged Orders and D Orders in the same manner following an Auction. This proposed rule text therefore makes clear that Primary Pegged Orders and D

[19] Current Rule 7.31(d)(4)(B)(i) provides ''[i]f a resting Limit Order on the Exchange Book is assigned a new display price and working price pursuant to Rule 7.31(a)(2)(C) and the PBBO is still locked or crossed, a resting D Order will also be assigned a new display price and working price pursuant to Rule 7.31(a)(2)(C).''

[20] The last clause of current Rule 7.31(h)(2)(B) provides: ''provided that, if a resting Limit Order on the Exchange Book is assigned a new display price and working price pursuant to Rule 7.31(a)(2)(C) and the PBBO is still locked or crossed, a resting Primary Pegged Order will also be assigned a new display price and working price pursuant to Rule 7.31(a)(2)(C).''

[21] The term ''UTP Security'' is defined in Rule 1.1(aa) to mean a security that is listed on a national securities exchange other than the Exchange and that trades on the Exchange pursuant to unlisted trading privileges and the term ''UTP Regulatory Halt'' is defined in Rule 1.1(z) to mean a trade suspension, halt, or pause caused by the UTP Listing Market in a UTP Security that requires all market centers to halt trading in that security. The term ''UTP Listing Market'' is defined in Rule 1.1(y) to mean the primary listing market for a UTP Security.

Orders would be assigned a display price and working price no differently than they would on arrival, as described in Rule 7.31.

• Finally, sell short orders would be priced to a Permitted Price as provided for under Rule 7.16(f)(5) (proposed Rule 7.35(f)(3)(A)(vi)). The Exchange proposes to reprice sell short orders last as the Permitted Price may have changed as a result of step one, described above (routing orders to the PBBO).

The Exchange believes that following a UTP Regulatory Halt or Auction, orders that would lock or cross the Away Market PBBO should either be routed (if routable) or cancelled (if non-routable) if they would be marketable against protected quotations on Away Markets. The Exchange believes that routing or cancelling such orders is consistent with Rule 610(d) because the Away Market does not have an obligation to prevent locking or crossing an Exchange quote in these scenarios. Therefore, in these scenarios, to prevent locking or crossing the Away Market PBBO, the Exchange would either route or cancel previously-entered orders before publishing a quote. This was how the Exchange processed orders following an Auction before it transitioned to Pillar.

Third, the Exchange proposes to apply the proposed processing of orders, described above, to odd-lot orders. In other words, odd-lot orders would no longer be processed differently than orders that are a round lot or greater in size. Currently, Rule 7.38(b)(1) and subparagraphs (A)–(C) describe how the working and display price of odd-lot orders are adjusted in relation to the contra-side PBBO. In short, currently, the working and display prices of odd-lot orders are bound by the PBBO, which means that resting odd-lot orders can be repriced if the PBBO changes or becomes locked or crossed.[22]

As proposed, odd-lot sized orders would be priced the same as orders of a round-lot size or higher, and if they are designated Priority 2—Display Orders, they would stand their ground if locked or crossed by an Away Market PBBO. To effect this change, the Exchange proposes to delete Rule 7.38(b)(1) and sub-paragraphs (A)–(C) in their entirety. The Exchange also proposes to delete the clause ''provided that'' at the end of Rule 7.38(b) and make a non-substantive change to that Rule to replace the term ''in'' with the term ''on.'' As a result of these changes, Rule 7.38(b) would provide, without any qualifiers, that ''[r]ound lot, mixed lot and odd-lot orders are treated in the same manner on the Exchange.'' The Exchange proposes an additional non-substantive change to renumber current Rule 7.38(b)(2) as Rule 7.38(c).

Fourth, because displayed odd-lot orders would stand their ground, the Exchange proposes to amend Rule 7.31(d)(1) to add new subparagraph (F) relating to Reserve Orders to specify new functionality of how non-routable Reserve Orders would be replenished if the display quantity of a resting Reserve Order is decremented to an odd-lot size when the PBBO is crossed. The Exchange proposes this change only for non-routable Reserve Orders. These changes are not necessary for a routable Reserve Order because when such order replenishes, the replenish quantity is evaluated for routing to Away Markets and thus would not be displayed at a price that crosses an Away Market.

As proposed in new subparagraph (F) to Rule 7.31(d)(1), if the PBBO is crossed and the display quantity of a Reserve Order to buy (sell) that is a Non-Routable Limit Order is decremented to less than a round lot, the display price and working price of the remaining odd-lot quantity of the Reserve Order would not change. This proposed rule text is consistent with the change, described above, that resting displayed orders, including odd-lot sized orders, would stand their ground if crossed by an Away Market. The proposed rule would further provide that the reserve interest that replenishes the display quantity would be assigned a display price one MPV below (above) the PBO (PBB) and a working price equal to the PBO (PBB). Because this is the first time such interest would be displayed, the Exchange proposes to adjust the display and working price so that the replenished quantity would not lock or cross the Away Market, which is the same manner that an arriving Non-Routable Limit Order is priced.[23]

When the PBBO uncrosses, the display price and working price would be adjusted as provided for under paragraph (e)(1) of this Rule relating to Non-Routable Limit Orders.

Fifth, as described above, displayed orders would stand their ground if locked or crossed by an Away Market. However, non-displayed orders do not. As set forth in Rule 7.31(d)(2)(A), the working price of a resting Non-Displayed Limit Order will be adjusted based on the limit price of the order. If the limit price of a Non-Displayed Limit Order to buy (sell) is at or below (above) the PBO (PBB), it will have a working price equal to the limit price. If the limit price of a Non-Displayed Limit Order to buy (sell) is above (below) the PBO (PBB), it will have a working price equal to the PBO (PBB). The Exchange proposes to amend Rule 7.31(d)(1) to provide that the working price of the reserve interest of resting Reserve Orders, which are non-displayed, would be adjusted in the same manner that the working price of Non-Displayed Limit Orders are adjusted.

To effect this change, the Exchange proposes to amend Rule 7.31(d)(1) to add the following sentence: ''The working price of the reserve interest of a resting Reserve Order will be adjusted in the same manner as a Non-Displayed Limit Order, as provided for in paragraph (d)(2)(A) of this Rule.'' The Exchange understands that at least one other exchange also adjusts the price of the non-displayed portion of Reserve Orders in the same manner that such exchange adjusts the price of non-displayed orders.[24]

Together with the proposed rule change described above to Rule 7.36(b), these rule changes make clear that on the Exchange, if crossed by an Away Market PBBO, displayed orders would stand their ground and non-displayed orders, including the reserve interest of resting Reserve Orders, would be repriced based off of the PBBO.

Implementation

Because of the technology changes associated with this proposed rule

[22] Current Rule 7.38(b)(1) provides that ''[t]he working and display price of an odd lot order will be adjusted both on arrival and when resting on the Exchange Book as follows: (A) If the limit price of an odd lot order to buy (sell) is at or below (above) the PBO (PBB), it will have a working and display price equal to the limit price. (B) If the limit price of an odd lot order to buy (sell) is above (below) the PBO (PBB), it will have a working price equal to the PBO (PBB). The display price will also be adjusted to the PBO (PBB) unless the order's instruction requires a display price that is different from the PBBO. (C) If the PBBO is locked or crossed and the limit price of an odd lot order to buy (sell) is above (below) the PBO (PBB), it will have a working and display price equal to the PBB (PBO). The working and display price of such odd lot order will not be adjusted again until the PBBO unlocks or uncrosses.''

[23] *See* Rule 7.31(e)(1)(A) (describing how arriving Non-Routable Limit Order is priced). On Nasdaq, a Price to Comply Order with Reserve Size replenishes in a similar manner. *See* Nasdaq Rule 4703(h); *see also* Supplementary Material .02 to IEX Rule 11.190(h) (''When a reserve order refreshes its displayed portion, the refreshing shares are not permitted to be displayed at a price that locks or crosses the price of a protected quotation on an away market and are subject to display-price sliding'').

[24] *See* IEX Rule 11.190(b)(2) (stating that the non-displayed portion of reserve orders are treated as non-displayed orders). IEX reprices its non-displayed orders differently from how the Exchange reprices Non-Displayed Limit Orders. *See* IEX Rule 11.190(h)(3)(D). Importantly, both IEX and the Exchange reprice non-displayed orders when crossed by an Away Market PBBO.

change, the Exchange will announce the implementation date of this proposed rule change by Trader Update. Subject to effectiveness of this proposed rule change, the Exchange anticipates that the implementation date will be in the Spring of 2020.

2. Statutory Basis

The Exchange believes that the proposal is consistent with Section 6(b) of the Act,[25] in general, and furthers the objectives of Sections 6(b)(5) of the Act,[26] in particular, because it is 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 mechanisms of, a free and open market and a national market system and, in general, to protect investors and the public interest and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that deleting Rule 7.31(a)(2)(C) and the related proposed amendment to Rule 7.36(b) to add new sub-paragraph (4) would remove impediments to and perfect the mechanism of a free and open market and a national market system because they would promote transparency in Exchange rules that previously-displayed orders would stand their ground if locked or crossed by an Away Market PBBO. The proposed rule changes would further promote transparency because they make clear that resting, displayed, depth-of-book orders that have been locked or crossed by an Away Market PBBO would be eligible to be disseminated to the SIP at their original price if they become the BBO.

The Exchange believes that previously-displayed orders, including depth-of-book orders, have priority at such price and should be able to stand their ground if locked or crossed by an Away Market. The Exchange therefore believes it is consistent with this principle to delete Rule 7.31(a)(2)(C) and change functionality on the Exchange for such orders to stand their ground and not be repriced if another market locks or crosses their price. The proposed change therefore benefits those resting orders because they would be able to keep their original working time and any priority ranking associated with such working time. The proposed change would also benefit liquidity takers, who would have greater certainty regarding the price at which they would receive an execution on the Exchange.

Moreover, the proposed change is consistent with how other exchanges function. While the rules of other exchanges differ in level of detail, these proposed changes are based in part on IEX Rules 11.190(h)(3)(A)(i) and (h)(3)(B)(i) and LTSE Rules 11.190(g)(3)(A)(i) and (g)(3)(B)(i), which similarly provide that previously-displayed orders on those exchanges maintain their display price and quantity if locked or crossed by an another market center. The proposal is also similar to how MEMX proposes it would function if approved as an exchange.

The Exchange further believes that these proposed amendments are consistent with Rule 610(d). If an Away Market publishes a PBBO that crosses not only the Exchange's BBO, but also resting, displayed, depth-of-book orders, it was the Away Market that crossed previously-displayed orders. If such previously-displayed, depth-of-book orders become the Exchange's BBO, the Exchange believes it is appropriate to disseminate those previously-displayed prices and quantities to the SIP as the new BBO because those resting orders pre-existed the Away Market quote that locked or crossed them.

For the same reasons, the Exchange believes that the proposed changes to D Orders and Primary Pegged Orders would remove impediments to and perfect the mechanism of a free and open market and a national market system because displayed orders that are pegged to a dynamic price would stand their ground at their original displayed price if locked or crossed by an Away Market, which is consistent with the proposed rule change that all displayed orders would stand their ground. These proposed rule changes also promote transparency by specifying that such orders would continue to be eligible to trade at their original working price, and that their display and working prices would not be adjusted until the PBBO is no longer locked or crossed.

The Exchange further believes that routing or cancelling orders that are marketable against an Away Market PBBO following a UTP Regulatory Halt or an Auction would also remove impediments to and perfect the mechanism of a free and open market and a national market system because in these scenarios, the Away Market would not have had an obligation to prevent displaying a locking or crossing quotation. The Exchange proposes to avoid locking or crossing an Away Market PBBO in these scenarios by routing or cancelling previously-displayed orders, as applicable. These proposed changes would reduce the number of times resting orders would be repriced, thereby increasing determinism for the price at which orders would be executed on the Exchange. The Exchange notes that this proposed change is not novel as this is how the Exchange processed orders following an auction before it transitioned NYSE-listed securities to Pillar.

The Exchange believes that processing odd-lot sized orders in the same manner as round-lot sized orders would remove impediments to and perfect the mechanism of a free and open market because the same principle applies: An order of any size that has been displayed has priority at that price if an Away Market subsequently locks or crosses that price. In addition, the Exchange believes that processing odd-lot orders the same as round-lot sized orders is not novel as it is consistent with the rules of other exchanges.[27]

Finally, the Exchange believes that the proposed changes to Reserve Orders would remove impediments to and perfect the mechanism of a free and open market because it would apply these principles to a Non-Routable Limit Order that is also a Reserve Order. This proposed functionality is also consistent with how Nasdaq and IEX process non-routable orders with reserve interest.[28] The proposed change to reprice the reserve interest of resting Reserve Orders in the same manner as a Non-Displayed Limit Order is priced would also remove impediments to and perfect the mechanism of a free and open market because it would promote consistency in Exchange rules regarding how similar orders are priced when crossed by an Away Market. The proposed change is also consistent with how IEX processes the reserve interest of Reserve Orders.[29]

[25] 15 U.S.C. 78f(b).

[26] 15 U.S.C. 78f(b)(5).

[27] *See, e.g.,* Nasdaq Rules 4703(b)(3) (defining the term ''odd lot'' as an order attribute) and 4702 (describing which order attributes are available for orders on Nasdaq, without any discussion of odd-lot sized orders being priced differently than round-lot sized orders). *See also* BZX Rules 11.10 (defining the term ''odd lot'') and 11.9 (describing BZX Orders and Modifiers, without any discussion of odd-lot sized orders being priced differently than round-lot sized orders).

[28] *See supra* note 23.

[29] *See supra* note 24.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[30] the Exchange believes that the proposed rule change would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed change is competitive because it is designed to conform how the Exchange processes previously-displayed orders with the functionality available on other exchanges, *i.e.,* that such orders would stand their ground if locked or crossed by an Away Market and be eligible to be disseminated to the SIP at their original price. The Exchange believes that the proposed change would promote competition because fewer orders would need to be repriced on the Exchange and therefore liquidity providers seeking for their orders to retain priority may route additional orders to the Exchange. Likewise, liquidity takers may be more likely to route orders to the Exchange if they have greater determinism regarding the price at which their orders would be executed.

Without this proposed rule change regarding how displayed orders would stand their ground if locked or crossed by an Away Market, the Exchange is currently at a competitive disadvantage vis-à-vis all other equity exchanges, which do not reprice orders in this manner. As discussed above, displayed orders on all other equity exchanges, including the two exchanges that recently had their Form 1 applications to be approved as an exchange (IEX and LTSE), stand their ground when locked or crossed by an Away Market and such orders are disseminated to the SIP if they become those exchanges' best bid or offer. In addition, MEMX proposes that displayed orders would stand their ground if locked or crossed by an Away Market.

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 such longer period 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–NYSE–2020–13 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2020–13. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2020–13, and should be submitted on or before April 8, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[31]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–05552 Filed 3–17–20; 8:45 am]

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[30] 15 U.S.C. 78f(b)(8).

[31] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–88363; File No. SR–NYSEAMER–2020–12]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing of Proposed Rule Change Amending Rule 7.31E (Orders and Modifiers) Relating to How Orders are Repriced and Make Related Changes to Rules 7.35E, 7.36E, and 7.38E

March 12, 2020.

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 February 28, 2020, NYSE American LLC (''NYSE American'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 7.31E (Orders and Modifiers) relating to how orders are repriced and make related changes to Rules 7.35E, 7.36E, and 7.38E. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

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 Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 7.31E (Orders and Modifiers) relating to how orders are repriced and make related changes to Rules 7.35E, 7.36E, and 7.38E.

Background

Currently, if an Away Market updates its PBBO and crosses not only the Exchange's BBO, but also displayed orders in the Exchange Book not represented in the BBO, *i.e.*, depth-of-book orders, and then the Exchange's BBO cancels or trades, the Exchange will not disseminate its next-best priced displayed order as its new BBO to the securities information processor (''SIP'').[3] Instead, the Exchange reprices such order before it is disseminated to the SIP.[4]

For example, if the Exchange's BB is $10.05 and on the Exchange Book, there is an order to buy 100 shares ranked Priority 2—Display Orders at $10.04 (''Order A''), Order A is displayed in the Exchange's proprietary depth-of-book market data at that $10.04 price but is not disseminated to the SIP.[5] If next, an Away Market publishes a PBO of $10.03, the Exchange's BB of $10.05 will stand its ground. However, if that $10.05 BB trades, cancels, or routes, the Exchange will not disseminate Order A to the SIP as the new BB at $10.04. Instead, as provided for in Rule 7.31E(a)(2)(C), Order A will be assigned a display price of $10.02 and a working price of $10.03, which is equal to the Away Market PBO, and will be disseminated to the SIP as the Exchange's BB at $10.02. Order A will be repriced to $10.04 once the Away Market PBBO no longer locks or crosses the Exchange BBO. Each time Order A is repriced, including back to its original price, it is assigned a new working time.[6] The Exchange also applies this repricing functionality following an auction.[7]

The Exchange believes that no other exchange reprices resting depth orders in this manner. The Exchange understands that in the same scenario on other exchanges, ''Order A'' would stand its ground and be disseminated to the SIP as their new BBO at $10.04, even if that price would cross the Away Market PBO of $10.03. The rules of other exchanges vary regarding how much detail is used to describe circumstances when displayed orders stand their ground, and none explicitly address the specific scenario described above, *i.e.,* when a resting, displayed, depth-of-book order is crossed by an Away Market quotation and then becomes the best-priced order on that exchange. For example:

- The Nasdaq Stock Market LLC (''Nasdaq'') Rule 4756(c)(2) provides that Nasdaq transmits for display to the appropriate network processor its best-priced orders. That Rule specifies exceptions of which orders are not transmitted to the SIP, *i.e.,* the reserve size of orders, the discretionary portion of Discretionary Orders, and Non-Displayed Orders. This rule is silent as to whether resting, displayed, depth-of-book orders that have been locked or crossed by another market center and then become the best-ranked orders on Nasdaq are transmitted to the SIP at their original price. Separately, Nasdaq rules provide that certain previously-displayed orders stand their ground. For example, pursuant to Nasdaq Rules 4702(b)(1)(B) and 4702(b)(2)(B), resting ''Price to Comply Orders'' and ''Price to Display Orders'' entered via RASH, QIX, or FIX will stand their ground if locked or crossed by another market center. But these rules discuss top-of-book displayed orders that are crossed, not depth-of-book orders.
- CBOE BZX Exchange, Inc. (''BZX'') Rule 11.12(b) (Priority of Orders) provides that the best-ranked order(s) to buy and the best-ranked order(s) to sell that are displayable in the BZX Book and the aggregated displayed size of such orders associated with such prices shall be collected and made available to quotation vendors for dissemination pursuant to the requirements of Rule 602 of Regulation NMS. This rule is silent as to whether resting, displayed, depth-of-book orders that have been locked or crossed by another market center and then become the best-ranked orders on BZX are transmitted to the SIP at their original price. BZX Rule 11.13(a)(2)(C) (Order Execution and Routing) discusses how orders execute on BZX when the PBBO is crossed, and how that exchange processes incoming orders during a crossed market. But that rule does not address the scenario described above regarding resting, displayed, depth-of-book orders and whether they would be made available to quotation vendors for dissemination at their original price, even when the PBBO is crossed. Under Rule 11.13(b)(4), BZX further provides for optional ''Re-Route Instructions'' pursuant to which if a routable order has been locked or crossed by another market, the routable order on the BZX book would be routed to that other market. However, these are optional instructions, which implies that in the absence of one of these instructions, if a routable order on BZX is locked or crossed by another market, such order stands its ground.
- Investors Exchange LLC (''IEX'') Rule 11.240(c)(1) provides that IEX disseminates the aggregate of its best-ranked displayable orders to quotation vendors for dissemination to the SIPs. IEX Rules 11.190(h)(3)(A)(i) and (h)(3)(B)(i) further provide that resting orders that are displayed at a price that later becomes locked or crossed, and were originally displayed in compliance with rules and regulations of IEX, will maintain their displayed price and quantity.[8] While these rules do not

[3] The term ''Away Market'' is defined in Rule 1.1E to mean ''any exchange, alternative trading system (''ATS'') or other broker-dealer (1) with which the Exchange maintains an electronic linkage and (2) that provides instantaneous responses to orders routed from the Exchange.'' The term ''BBO'' is defined in Rule 1.1E to mean the best bid or offer on the Exchange, and the term ''BB'' means the best bid on the Exchange, and the term ''BO'' means the best offer on the Exchange. The term ''PBB'' is defined in Rule 1.1E to mean the highest Protected Bid, the term ''PBO'' means the lowest Protected Offer, and ''PBBO'' means the Best Protected Bid and Best Protected Offer. The terms ''Protected Bid'' and ''Protected Offer'' are defined in Rule 1.1E. The term ''Exchange Book'' is defined in Rule 1.1E to mean the Exchange's electronic file of orders, which contains all orders entered on the Exchange.

[4] *See* Rule 7.31E(a)(2)(C), which provides that ''[i]If a BB (BO) that is locked or crossed by an Away Market PBO (PBB) is cancelled, executed or routed and the next best-priced resting Limit Order(s) on the Exchange Book that would become the new BB (BO) would have a display price that would lock or cross the PBO (PBB), such Limit Order(s) to buy (sell) will be assigned a display price one MPV below (above) the PBO (PBB) and a working price equal to the PBO (PBB). When the PBO (PBB) is updated, the Limit Order(s) to buy (sell) will be repriced consistent with the original terms of the order. If a Day ISO to buy (sell) arrives before the PBO (PBB) is updated, such repriced Limit Order(s) to buy (sell) will be repriced to the lower (higher) of the display price of the Day ISO or the original price of the Limit Order(s).''

[5] *See* Rule 7.36E(b)(3) (describing which orders are collected and made available to quotation vendors for dissemination pursuant to the requirements of Rule 602 under Regulation NMS under the Act).

[6] *See* Rule 7.36E(f)(2) (an order is assigned a new working time any time its working price changes).

[7] *See* Rule 7.35E(h)(3)(A).

[8] *See also* Supplementary Material .02 to Rule 11.190(h) (providing that ''[o]rders displayed on the Exchange which were displayed at a price compliant with Regulation NMS are generally permitted to maintain their displayed price in the

Continued

distinguish between displayed orders at the top of the IEX book and depth-of-book displayed orders, these rules appear consistent with the Exchange's proposed change to provide that resting, displayed, depth-of-book orders would stand their ground and are eligible to be disseminated to the SIP as the BBO at their original displayed price.

• Long-Term Stock Exchange (''LTSE'') Rule 11.240(c)(1) provides that LTSE disseminates the aggregate of its best-ranked displayable orders to quotation vendors for dissemination to the SIPs.[9] LTSE Rules 11.190(g)(3)(A)(i) and (g)(3)(B)(i) further provide that resting orders that are displayed at a price that later becomes locked or crossed, and were originally displayed in compliance with rules and regulations of LTSE, will maintain their displayed price and quantity.[10] While these rules do not distinguish between displayed orders at the top of the LTSE book and at depth, these rules appear consistent with the Exchange's proposed change to provide that resting, displayed, depth-of-book orders would stand their ground and are eligible to be disseminated to the SIP as the BBO at their original displayed price.

• MEMX LLC (''MEMX'') has filed a Form 1 application for registration as a national securities exchange pursuant to Section 6 of the Act.[11] Proposed MEMX Rule 11.9(b) provides that the best-ranked order(s) to buy and the best-ranked order(s) to sell that are displayable in the MEMX Book and the aggregate displayed size of such orders associated with such prices shall be collected and made available to the SIP. MEMX claims that its proposed MEMX Rule 11.6(j)(1)(A)(ii), which provides that ''[f]ollowing the initial ranking and display or an order subject to the Display-Price Sliding instruction, an order will only be re-ranked and re-displayed to the extent it achieves a more aggressive price, provided, however, that the Exchange will re-rank an order at the same price as the displayed price in the event such orders' displayed price would be a Locking or Crossing Quotation'' makes clear that an order displayed by MEMX would not be re-priced to a less aggressive price if another market locked or crossed an order displayed by MEMX.[12] The Exchange understands this response to mean that MEMX would not re-price displayed orders that were at depth that would become the MEMX best bid or offer.

The Exchange proposes to amend its rules to conform how it reprices orders in this scenario to how other exchanges function. The Exchange believes that because such orders did not lock or cross an Away Market PBBO when they were entered on the Exchange and displayed to the Exchange's proprietary market data, such resting orders have priority at the price at which they were originally displayed.[13] In other words, such resting orders did not cause a locked or crossed market condition.

The Exchange further believes that providing priority to such resting orders on the Exchange Book (*e.g.,* disseminating ''Order A'' as a BB at $10.04 in the above-described scenario) would be consistent with Rule 610(d) under the Act (''Rule 610(d)'').[14] Rule 610(d) provides that ''[e]ach national securities exchange . . . shall establish, maintain, and enforce written rules that . . . are reasonably designed to assure the reconciliation of locked quotations in an NMS stock.'' The proposed rule change is consistent with this requirement because in the scenario described above, the Away Market has published a PBO that crosses not only the Exchange's BB, but also other orders that have already been entered on the Exchange and displayed on the Exchange's proprietary market data. Even though such depth-of-book orders have not yet been disseminated to the SIP as part of the Exchange's BBO, those resting orders pre-exist the Away Market quote that crossed them. Therefore, disseminating any pre-existing, displayed orders to the SIP as the new BB at their original price would be consistent with Rule 610(d) because it was the Away Market that crossed previously-displayed orders.

Proposed Rule Change

To effect this proposed rule change, the Exchange proposes to delete Rule 7.31E(a)(2)(C) in its entirety. The Exchange also proposes to delete references to this Rule and describe how the Exchange would process orders, as follows.

First, the Exchange proposes rule changes to specify that previously-displayed orders at any price stand their ground and remain eligible to be quoted or traded at their last-displayed price, even if locked or crossed by an Away Market. The Exchange proposes to specify this principal generally for all displayed orders by amending Rule 7.36E(b) to add new subparagraph (4) that would provide that if an Away Market locks or crosses the BBO, the Exchange would not change the display price of any Limit Order ranked Priority 2—Display Orders[15] and any such orders would be eligible to be disseminated as the Exchange's BBO.[16] This proposed rule text both (1) provides specificity that all resting, top-of-book displayed orders stand their ground, which is current functionality,[17] and (2) describes new functionality for previously displayed depth-of-book orders, which would now stand their ground instead of being repriced if they become the Exchange's BBO.

Because such resting orders would no longer be repriced if locked or crossed by an Away Market, such orders would not need to be assigned new working times and would therefore retain priority at their original price. In addition, for market participants that read the Exchange's proprietary market data and are aware of displayed, depth-of-book orders, this proposed change provides greater certainty regarding the price at which a liquidity-taking order would execute on the Exchange.

This proposed rule text therefore promotes transparency and clarity in Exchange rules that all resting, displayed orders, including depth-of-book orders, would stand their ground if locked or crossed by an Away Market. Proposed Rule 7.36E(b)(4) is based in

event an away trading center locks or crosses the price of the IEX displayed order.'')

[9] LTSE has been approved as a registered exchange but is not yet operational.

[10] *See also* Supplementary Material .02 to LTSE Rule 11.190(g).

[11] *See* Securities Exchange Act Release No. 87436 (October 31, 2019), 84 FR 59854 (November 6, 2019) (File No. 1—237). Although MEMX has not yet been approved as an exchange, the Exchange believes that its proposed rules are relevant to this discussion as MEMX expects to be operational in 2020, subject to approval of its Form 1 application.

[12] *See* Letter from Anders Franzon, General Counsel, MEMX, to Ms. Vanessa Countryman, Secretary, Securities and Exchange Commission, dated February 11, 2020, available here: *https://www.sec.gov/comments/10-237/10237-6795399-208386.pdf.*

[13] If the PBBO is locked or crossed at the time of an order's arrival, such arriving orders would be either routed, cancelled, or repriced, as provided for in Rule 7.37(c) (for routable orders) or Rule 7.31E(e) (for non-routable orders). This proposed rule change is applicable only to resting orders.

[14] 17 CFR 242.610(d).

[15] As set forth in Rule 7.36E(c), all non-marketable orders are ranked and maintained in the Exchange Book in the following manner: (1) Price; (2) priority category; (3) time; and (4) ranking restrictions applicable to an order or modifier condition. Under Rule 7.36E(e)(2), ''Priority 2—Display Orders'' are non-marketable Limit Orders with a displayed working price. Limit Orders that are ranked Priority 2—Display Orders can be top of book or at depth.

[16] As set forth in Rule 7.36E(b)(1), the Exchange considers an order to be ''displayed'' when it has been disseminated via a market data feed. Because all orders ranked Priority 2—Display Orders, regardless of price, are displayed via proprietary data feeds, such orders are all ''displayed'' for purposes of Exchange rules.

[17] Current Rule 7.31E(e)(1)(A)(iii) specifies that Non-Routable Limit Orders stand their ground when crossed by an Away Market PBBO.

part on IEX Rules 11.190(h)(3)(A)(i) and (h)(3)(B)(i) and LTSE Rules 11.190(g)(3)(A)(i) and (g)(3)(B)(i), described above, and is consistent with proposed MEMX Rule 11.6(j)(1)(A)(ii).

Second, the Exchange proposes to specify how the Exchange would process orders following either a UTP Regulatory Halt in a UTP Security or an Auction that is not preceded by continuous trading.[18] Because continuous trading did not precede either of these scenarios, the Exchange does not have a displayed quote eligible to stand its ground. Accordingly, to prevent publishing a quote that would lock or cross an Away Market, the Exchange proposes that before the Exchange publishes a quote following either of these scenarios, orders that are marketable against a protected quotation on an Away Market would be either routed (if routable) or cancelled (if non-routable).

The second clause of proposed Rule 7.36E(b)(4) would address how the Exchange would process orders before resuming trading and publishing a quote in a UTP Security following a UTP Regulatory Halt. This proposed rule text would be an exception to the first half of the rule text, described above, that previously-displayed orders stand their ground. The Exchange proposes this exception because during a UTP Regulatory Halt, there is no continuous trading and the Exchange ''zeroes'' out its quote, meaning the Exchange removes its BBO from the SIP. However, during a UTP Regulatory Halt, the Exchange may still have orders on its book. Specifically, as set forth in Rule 7.18E(b), during a UTP Regulatory Halt, the Exchange cancels resting non-displayed orders and maintains all other resting orders in the Exchange Book at their last working price and display price. The Exchange does not accept new orders during such a halt. As provided for in Rule 7.18E(a), the Exchange does not resume trading, including publishing a quote, in such security until it receives notification from the UTP Listing Market that the halt or suspension is no longer in effect and it has received the first Price Band in that security. The Exchange proposes that once it is eligible to resume trading, previously-displayed Limit Orders, *i.e.,* the orders entered before the UTP Regulatory Halt, would be routed (if routable) or cancelled (if non-routable) if such orders would be marketable against protected quotations on Away Markets.

For example, if before a UTP Regulatory Halt in XYZ security, the Exchange's BBO was $10.10 (100 shares) × $10.12 (100 shares), and before the Exchange resumes trading following that UTP Regulatory Halt, the first PBBO is $10.08 (100 shares) × $10.09 (100 shares), because the Exchange's former best bid of $10.10 is marketable against the new $10.09 PBO, the Exchange would either route that order (if routable) or cancel it (if non-routable). The Exchange would publish the former $10.12 because it is not marketable against an Away Market quotation.

To specify how orders would be processed before publishing a quote when transitioning from a prior trading session or following the Core Open or Closing Auction, *i.e.,* transitions preceded by continuous trading and the Exchange has a published quote immediately preceding the transition, the Exchange proposes that those displayed orders are eligible to stand their ground, as described in proposed Rule 7.36E(b)(4), above. To effect this change, the Exchange proposes to delete the last clause of Rule 7.35E(h)(3)(A)(i), which provides that if the new published quote is worse than the previously-published quote and would lock or cross the PBBO, the display price of Limit Orders will be adjusted consistent with Rule 7.31E(a)(2)(C). This proposed change is consistent with the proposed change to Rule 7.36E(b), described above, that previously-displayed orders stand their ground if crossed by an Away Market. Because this paragraph is about scenarios where an Auction follows continuous trading and there was a previously-published quote, the Exchange also proposes a non-substantive, clarifying amendment to Rule 7.35E(h)(3)(A)(i) to specify that this subparagraph of the Rule would be applicable to Closing Auctions that are preceded by continuous trading.

To specify how orders would be processed before publishing a quote when transitioning to continuous trading following an Auction that is not preceded by continuous trading, the Exchange proposes to amend Rule 7.35E(h)(3)(A)(ii). Currently, before publishing a quote following a Trading Halt Auction or IPO Auction: (1) Previously-live Limit Orders that are designated with a Proactive if Locked/Crossed Modifier or that would be the result of reserve interest replenishing the display quantity of a routable Reserve Order will route, if marketable against protected quotations on Away Markets; (2) for the Trading Halt Auction only, previously-live orders that are marketable against other orders in the Exchange Book and that would not trade through a protected quotation will trade; and (3) the display price of all other orders that are marketable against a protected quotation on an Away Market will be adjusted consistent with Rule 7.31E(a)(2)(C).

Because the Exchange will no longer be adjusting the price of orders as provided for in Rule 7.31E(a)(2)(C), the Exchange proposes that, generally, to prevent publishing a quote that would lock or cross an Away Market PBBO, following an Auction that is not preceded by continuous trading, if orders are marketable against protected quotations on Away Markets, routable orders would route and non-routable orders would cancel. To effect this change, the Exchange proposes to amend Rule 7.35E(h)(3)(A)(ii) to provide that, before publishing a quote following a Trading Halt Auction or IPO Auction (or Closing Auction if not preceded by continuous trading), previously-live orders would be processed as follows:

- Orders eligible to route that are marketable against protected quotations on Away Markets would route based on the ranking of such orders as set forth in Rule 7.36E(c) (proposed Rule 7.35E(h)(3)(A)(ii)(a)). With this proposed change, routable orders at potentially multiple price points would be routed to protected quotations on Away Markets before any other action is taken.
- After routing eligible orders, orders not eligible to route (excluding during a Short Sale Price Test, sell short orders) that are marketable against protected quotations on Away Markets would cancel (proposed Rule 7.35E(h)(3)(A)(ii)(b)). During a Short Sale Price Test, the Exchange does not propose to route sell short orders, because such orders, by their terms, are eligible to be repriced.
- Once there are no more unexecuted orders marketable against protected quotations on Away Markets (because they have either been routed or cancelled), orders that are marketable against other orders in the Exchange Book would trade (proposed Rule 7.35E(h)(3)(A)(ii)(c)). With this proposed step, remaining orders on the Exchange book that could trade would trade.
- The display quantity of Reserve Orders would be replenished as provided for in Rule 7.31E(d)(1) (proposed Rule 7.35E(h)(3)(A)(ii)(d)).

[18] The term ''UTP Security'' is defined in Rule 1.1E to mean a security that is listed on a national securities exchange other than the Exchange and that trades on the Exchange pursuant to unlisted trading privileges and the term ''UTP Regulatory Halt'' is defined in Rule 1.1E to mean a trade suspension, halt, or pause caused by the UTP Listing Market in a UTP Security that requires all market centers to halt trading in that security. The term ''UTP Listing Market'' is defined in Rule 1.1E to mean the primary listing market for a UTP Security.

• Finally, sell short orders would be priced to a Permitted Price as provided for under Rule 7.16E(f)(5) (proposed Rule 7.35E(h)(3)(A)(ii)(e)). The Exchange proposes to reprice sell short orders last as the Permitted Price may have changed as a result of step one, described above (routing orders to the PBBO).

The Exchange believes that following an Auction that is not preceded by continuous trading, orders that would lock or cross the Away Market PBBO should either be routed (if routable) or cancelled (if non-routable) if they would be marketable against protected quotations on Away Markets. The Exchange believes that routing or cancelling such orders is consistent with Rule 610(d) because the Away Market does not have an obligation to prevent locking or crossing an Exchange quote in these scenarios. Therefore, in these scenarios, to prevent locking or crossing the Away Market PBBO, the Exchange would either route or cancel previously-entered orders before publishing a quote. This was how New York Stock Exchange, LLC (''NYSE'') processed orders following an Auction before it transitioned to Pillar.

The Exchange also proposes a non-substantive change regarding how the term ''previously-live orders' is defined for purposes of Rule 7.35E(h)(3)(A). Currently, the term ''previously-live orders'' is defined as unexecuted orders that were eligible to trade in the trading session both before and after the transition or auction. This definition is intended to refer to the trading session designated for an order, not that it was eligible to trade in continuous trading, and include orders that were entered during a trading halt that occurred in the same trading session as the auction. To clarify this rule, the Exchange proposes to amend Rule 7.35E(h)(3)(A) and define a ''previously-live order'' as an unexecuted order that was received before the Auction Processing Period and was designated to trade in the trading session both before and after the transition or auction.

Third, the Exchange proposes to apply the proposed processing of orders, described above, to odd-lot orders. In other words, odd-lot orders would no longer be processed differently than orders that are a round lot or greater in size. Currently, Rule 7.38E(b)(1) and subparagraphs (A)–(C) describe how the working and display price of odd-lot orders are adjusted in relation to the contra-side PBBO. In short, currently, the working and display prices of odd-lot orders are bound by the PBBO, which means that resting odd-lot orders can be repriced if the PBBO changes or becomes locked or crossed.[19]

As proposed, odd-lot sized orders would be priced the same as orders of a round-lot size or higher, and if they are designated Priority 2—Display Orders, they would stand their ground if locked or crossed by an Away Market PBBO. To effect this change, the Exchange proposes to delete Rule 7.38E(b)(1) and sub-paragraphs (A)–(C) in their entirety. The Exchange also proposes to delete the clause ''provided that'' at the end of Rule 7.38E(b) and make a non-substantive change to that Rule to replace the term ''in'' with the term ''on.'' As a result of these changes, Rule 7.38E(b) would provide, without any qualifiers, that ''[r]ound lot, mixed lot and odd-lot orders are treated in the same manner on the Exchange.'' The Exchange proposes an additional non-substantive change to renumber current Rule 7.38E(b)(2) as Rule 7.38E(c).

Fourth, because displayed odd-lot orders would stand their ground, the Exchange proposes to amend Rule 7.31E(d)(1) to add new subparagraph (F) relating to Reserve Orders to specify new functionality of how non-routable Reserve Orders would be replenished if the display quantity of a resting Reserve Order is decremented to an odd-lot size when the PBBO is crossed. The Exchange proposes this change only for non-routable Reserve Orders. These changes are not necessary for a routable Reserve Order because when such order replenishes, the replenish quantity is evaluated for routing to Away Markets and thus would not be displayed at a price that crosses an Away Market.

As proposed in new subparagraph (F) to Rule 7.31E(d)(1), if the PBBO is crossed and the display quantity of a Reserve Order to buy (sell) that is a Non-Routable Limit Order is decremented to less than a round lot, the display price and working price of such Reserve Order would not change. This proposed rule text is consistent with the change, described above, that resting displayed orders, including odd-lot sized orders, would stand their ground if crossed by an Away Market. The proposed rule would further provide that the reserve interest that replenishes the display quantity would be assigned a display price one MPV below (above) the PBO (PBB) and a working price equal to the PBO (PBB). Because this is the first time such interest would be displayed, the Exchange proposes to adjust the display and working price so that the replenished quantity would not lock or cross the Away Market, which is the same manner that an arriving Non-Routable Limit Order is priced.[20]

When the PBBO uncrosses, the display price and working price would be adjusted as provided for under paragraph (e)(1) of this Rule relating to Non-Routable Limit Orders.

Fifth, as described above, displayed orders would stand their ground if locked or crossed by an Away Market. However, non-displayed orders do not. As set forth in Rule 7.31E(d)(2)(A), the working price of a resting Non-Displayed Limit Order will be adjusted based on the limit price of the order. If the limit price of a Non-Displayed Limit Order to buy (sell) is at or below (above) the PBO (PBB), it will have a working price equal to the limit price. If the limit price of a Non-Displayed Limit Order to buy (sell) is above (below) the PBO (PBB), it will have a working price equal to the PBO (PBB). The Exchange proposes to amend Rule 7.31(d)(1) to provide that the working price of the reserve interest of resting Reserve Orders, which are non-displayed, would be adjusted in the same manner that the working price of Non-Displayed Limit Orders are adjusted.

To effect this change, the Exchange proposes to amend Rule 7.31E(d)(1) to add the following sentence: ''The working price of the reserve interest of a resting Reserve Order will be adjusted in the same manner as a Non-Displayed Limit Order, as provided for in paragraph (d)(2)(A) of this Rule.'' The Exchange understands that at least one other exchange also adjusts the price of the non-displayed portion of Reserve Orders in the same manner that such

[19] Current Rule 7.38E(b)(1) provides that ''[t]he working and display price of an odd lot order will be adjusted both on arrival and when resting on the Exchange Book as follows: (A) If the limit price of an odd lot order to buy (sell) is at or below (above) the PBO (PBB), it will have a working and display price equal to the limit price. (B) If the limit price of an odd lot order to buy (sell) is above (below) the PBO (PBB), it will have a working price equal to the PBO (PBB). The display price will also be adjusted to the PBO (PBB) unless the order's instruction requires a display price that is different from the PBBO. (C) If the PBBO is locked or crossed and the limit price of an odd lot order to buy (sell) is above (below) the PBO (PBB), it will have a working and display price equal to the PBB (PBO). The working and display price of such odd lot order will not be adjusted again until the PBBO unlocks or uncrosses.''

[20] *See* Rule 7.31E(e)(1)(A) (describing how arriving Non-Routable Limit Order is priced). On Nasdaq, a Price to Comply Order with Reserve Size replenishes in a similar manner. *See* Nasdaq Rule 4703(h); *see also* Supplementary Material .02 to IEX Rule 11.190(h) (''When a reserve order refreshes its displayed portion, the refreshing shares are not permitted to be displayed at a price that locks or crosses the price of a protected quotation on an away market and are subject to display-price sliding'').

exchange adjusts the price of non-displayed orders.[21]

Together with the proposed rule change described above to Rule 7.36E(b), these rule changes make clear that on the Exchange, if crossed by an Away Market PBBO, displayed orders would stand their ground and non-displayed orders, including the reserve interest of resting Reserve Orders, would be repriced based off of the PBBO.

Implementation

Because of the technology changes associated with this proposed rule change, the Exchange will announce the implementation date of this proposed rule change by Trader Update. Subject to effectiveness of this proposed rule change, the Exchange anticipates that the implementation date will be in the Spring of 2020.

2. Statutory Basis

The Exchange believes that the proposal is consistent with Section 6(b) of the Act,[22] in general, and furthers the objectives of Sections 6(b)(5) of the Act,[23] in particular, because it is 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 mechanisms of, a free and open market and a national market system and, in general, to protect investors and the public interest and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that deleting Rule 7.31E(a)(2)(C) and the related proposed amendment to Rule 7.36E(b) to add new sub-paragraph (4) would remove impediments to and perfect the mechanism of a free and open market and a national market system because they would promote transparency in Exchange rules that previously-displayed orders would stand their ground if locked or crossed by an Away Market PBBO. The proposed rule changes would further promote transparency because they make clear that resting, displayed, depth-of-book orders that have been locked or crossed by an Away Market PBBO would be eligible to be disseminated to the SIP at their original price if they become the BBO.

The Exchange believes that previously-displayed orders, including depth-of-book orders, have priority at such price and should be able to stand their ground if locked or crossed by an Away Market. The Exchange therefore believes it is consistent with this principle to delete Rule 7.31E(a)(2)(C) and change functionality on the Exchange for such orders to stand their ground and not be repriced if another market locks or crosses their price. The proposed change therefore benefits those resting orders because they would be able to keep their original working time and any priority ranking associated with such working time. The proposed change would also benefit liquidity takers, who would have greater certainty regarding the price at which they would receive an execution on the Exchange.

Moreover, the proposed change is consistent with how other exchanges function. While the rules of other exchanges differ in level of detail, these proposed changes are based in part on IEX Rules 11.190(h)(3)(A)(i) and (h)(3)(B)(i)and LTSE Rules 11.190(g)(3)(A)(i) and (g)(3)(B)(i), which similarly provide that previously-displayed orders on those exchanges maintain their display price and quantity if locked or crossed by an another market center. The proposal is also similar to how MEMX proposes it would function if approved as an exchange.

The Exchange further believes that these proposed amendments are consistent with Rule 610(d). If an Away Market publishes a PBBO that crosses not only the Exchange's BBO, but also resting, displayed, depth-of-book orders, it was the Away Market that crossed previously-displayed orders. If such previously-displayed, depth-of-book orders become the Exchange's BBO, the Exchange believes it is appropriate to disseminate those previously-displayed prices and quantities to the SIP as the new BBO because those resting orders pre-existed the Away Market quote that locked or crossed them.

The Exchange further believes that routing or cancelling orders that are marketable against an Away Market PBBO following a UTP Regulatory Halt or an Auction that is not preceded by continuous trading would also remove impediments to and perfect the mechanism of a free and open market and a national market system because in these scenarios, the Away Market would not have had an obligation to prevent displaying a locking or crossing quotation. The Exchange proposes to avoid locking or crossing an Away Market PBBO in these scenarios by routing or cancelling previously-displayed orders, as applicable. These proposed changes would reduce the number of times resting orders would be repriced, thereby increasing determinism for the price at which orders would be executed on the Exchange. The Exchange notes that this proposed change is not novel as this is how NYSE processed orders following an auction before it transitioned NYSE-listed securities to Pillar. The Exchange further believes that the proposed change to the definition of ''previously-live orders'' would remove impediments to and perfect the mechanism of a free and open market and a national market system because the proposed rule text is designed to clarify the existing rule without changing its meaning, thus promoting transparency and clarity in Exchange rules.

The Exchange believes that processing odd-lot sized orders in the same manner as round-lot sized orders would remove impediments to and perfect the mechanism of a free and open market because the same principle applies: An order of any size that has been displayed has priority at that price if an Away Market subsequently locks or crosses that price. In addition, the Exchange believes that processing odd-lot orders the same as round-lot sized orders is not novel as it is consistent with the rules of other exchanges.[24]

Finally, the Exchange believes that the proposed changes to Reserve Orders would remove impediments to and perfect the mechanism of a free and open market because it would apply these principles to a Non-Routable Limit Order that is also a Reserve Order. This proposed functionality is also consistent with how Nasdaq and IEX process non-routable orders with reserve interest.[25] The proposed change to reprice the reserve interest of resting Reserve Orders in the same manner as a Non-Displayed Limit Order is priced would also remove impediments to and perfect the mechanism of a free and open market because it would promote consistency in Exchange rules regarding

[21] *See* IEX Rule 11.190(b)(2) (stating that the non-displayed portion of reserve orders are treated as non-displayed orders). IEX reprices its non-displayed orders differently from how the Exchange reprices Non-Displayed Limit Orders. *See* IEX Rule 11.190(h)(3)(D). Importantly, both IEX and the Exchange reprice non-displayed orders when crossed by an Away Market PBBO.

[22] 15 U.S.C. 78f(b).

[23] 15 U.S.C. 78f(b)(5).

[24] *See, e.g.,* Nasdaq Rules 4703(b)(3) (defining the term ''odd lot'' as an order attribute) and 4702 (describing which order attributes are available for orders on Nasdaq, without any discussion of odd-lot sized orders being priced differently than round-lot sized orders). *See also* BZX Rules 11.10 (defining the term ''odd lot'') and 11.9 (describing BZX Orders and Modifiers, without any discussion of odd-lot sized orders being priced differently than round-lot sized orders).

[25] *See supra* note 20.

how similar orders are priced when crossed by an Away Market. The proposed change is also consistent with how IEX processes the reserve interest of Reserve Orders.[26]

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[27] the Exchange believes that the proposed rule change would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed change is competitive because it is designed to conform how the Exchange processes previously-displayed orders with the functionality available on other exchanges, *i.e.,* that such orders would stand their ground if locked or crossed by an Away Market and be eligible to be disseminated to the SIP at their original price. The Exchange believes that the proposed change would promote competition because fewer orders would need to be repriced on the Exchange and therefore liquidity providers seeking for their orders to retain priority may route additional orders to the Exchange. Likewise, liquidity takers may be more likely to route orders to the Exchange if they have greater determinism regarding the price at which their orders would be executed.

Without this proposed rule change regarding how displayed orders would stand their ground if locked or crossed by an Away Market, the Exchange is currently at a competitive disadvantage vis-à-vis all other equity exchanges, which do not reprice orders in this manner. As discussed above, displayed orders on all other equity exchanges, including the two exchanges that recently had their Form 1 applications to be approved as an exchange (IEX and LTSE), stand their ground when locked or crossed by an Away Market and such orders are disseminated to the SIP if they become those exchanges' best bid or offer. In addition, MEMX proposes that displayed orders would stand their ground if locked or crossed by an Away Market.

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.

[26] *See supra* note 21.

[27] 15 U.S.C. 78f(b)(8).

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 such period 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–NYSEAMER–2020–12 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–NYSEAMER–2020–12. 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–NYSEAMER–2020–12, and should be submitted on or before April 8, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[28]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–05553 Filed 3–17–20; 8:45 am]

BILLING CODE 8011–01–P

[28] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–88364; File No. SR–NYSEArca–2020–07]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change Relating to Listing and Trading of Shares of the SPDR SSGA Responsible Reserves ESG ETF Under NYSE Arca Rule 8.600–E

March 12, 2020.

On January 14, 2020, NYSE Arca, Inc. 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 shares of the SPDR SSGA Responsible Reserves ESG ETF under NYSE Arca Rule 8.600–E. The proposed rule change was published for comment in the **Federal Register** on January 30, 2020.[3] The Commission has received no comment letters on the proposed rule change.

Section 19(b)(2) of the Act [4] 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 will either approve the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 88031 (Jan. 24, 2020), 85 FR 5493.

[4] 15 U.S.C. 78s(b)(2).

proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is March 15, 2020. The Commission is extending this 45-day time period.

The Commission finds it appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[5] designates April 29, 2020 as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR–NYSEArca–2020–07).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–05554 Filed 3–17–20; 8:45 am]

BILLING CODE 8011–01–P

[5] *Id.*

[6] 17 CFR 200.30–3(a)(31).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–88367; File No. SR–NYSECHX–2020–06]

Self-Regulatory Organizations; NYSE Chicago, Inc.; Notice of Filing of Proposed Rule Change Amending Rule 7.31 (Orders and Modifiers) Relating to How Orders Are Repriced and Make Related Changes to Rules 7.36 and 7.38

March 12, 2020.

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 February 28, 2020, the NYSE Chicago, Inc. (''NYSE Chicago'' or the ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 7.31 (Orders and Modifiers) relating to how orders are repriced and make related changes to Rules 7.36 and 7.38. 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 Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 7.31 (Orders and Modifiers) relating to how orders are repriced and make related changes to Rules 7.36 and 7.38.

Background

Currently, if an Away Market updates its PBBO and crosses not only the Exchange's BBO, but also displayed orders in the Exchange Book not represented in the BBO, *i.e.,* depth-of-book orders, and then the Exchange's BBO cancels or trades, the Exchange will not disseminate its next-best priced displayed order as its new BBO to the securities information processor (''SIP'').[4] Instead, the Exchange reprices such order before it is disseminated to the SIP.[5]

For example, if the Exchange's BB is $10.05 and on the Exchange Book, there is an order to buy 100 shares ranked Priority 2—Display Orders at $10.04 (''Order A''), Order A is displayed in the Exchange's proprietary depth-of-book market data at that $10.04 price but is not disseminated to the SIP.[6] If next, an Away Market publishes a PBO of $10.03, the Exchange's BB of $10.05 will stand its ground. However, if that $10.05 BB trades, cancels, or routes, the Exchange will not disseminate Order A to the SIP as the new BB at $10.04. Instead, as provided for in Rule 7.31(a)(2)(C), Order A will be assigned a display price of $10.02 and a working price of $10.03, which is equal to the Away Market PBO, and will be disseminated to the SIP as the Exchange's BB at $10.02. Order A will be repriced to $10.04 once the Away Market PBBO no longer locks or crosses the Exchange BBO. Each time Order A is repriced, including back to its original price, it is assigned a new working time.[7] The Exchange also applies this repricing functionality to Primary Pegged Orders.[8]

The Exchange believes that no other exchange reprices resting depth orders in this manner. The Exchange understands that in the same scenario on other exchanges, ''Order A'' would stand its ground and be disseminated to the SIP as their new BBO at $10.04, even if that price would cross the Away Market PBO of $10.03. The rules of other exchanges vary regarding how much detail is used to describe circumstances when displayed orders stand their ground, and none explicitly address the specific scenario described above, *i.e.,* when a resting, displayed, depth-of-book order is crossed by an Away Market quotation and then

[4] The term ''Away Market'' is defined in Rule 1.1(b) to mean ''any exchange, alternative trading system (''ATS'') or other broker-dealer (1) with which the Exchange maintains an electronic linkage and (2) that provides instantaneous responses to orders routed from the Exchange.'' The term ''BBO'' is defined in Rule 1.1(c) to mean the best bid or offer on the Exchange, and the term ''BB'' means the best bid on the Exchange, and the term ''BO'' means the best offer on the Exchange. The term ''PBB'' is defined in Rule 1.1(n) to mean the highest Protected Bid, the term ''PBO'' means the lowest Protected Offer, and ''PBBO'' means the Best Protected Bid and Best Protected Offer. The terms ''Protected Bid'' and ''Protected Offer'' are defined in Rule 1.1(q). The term ''Exchange Book'' is defined in Rule 1.1(j) to mean the Exchange's electronic file of orders, which contains all orders entered on the Exchange.

[5] *See* Rule 7.31(a)(2)(C), which provides that ''[i]f a BB (BO) that is locked or crossed by an Away Market PBO (PBB) is cancelled, executed or routed and the next best-priced resting Limit Order(s) on the Exchange Book that would become the new BB (BO) would have a display price that would lock or cross the PBO (PBB), such Limit Order(s) to buy (sell) will be assigned a display price one MPV below (above) the PBO (PBB) and a working price equal to the PBO (PBB). When the PBO (PBB) is updated, the Limit Order(s) to buy (sell) will be repriced consistent with the original terms of the order. If a Day ISO to buy (sell) arrives before the PBO (PBB) is updated, such repriced Limit Order(s) to buy (sell) will be repriced to the lower (higher) of the display price of the Day ISO or the original price of the Limit Order(s).''

[6] *See* Rule 7.36(b)(3) (describing which orders are collected and made available to quotation vendors for dissemination pursuant to the requirements of Rule 602 under Regulation NMS under the Act).

[7] *See* Rule 7.36(f)(2) (an order is assigned a new working time any time its working price changes).

[8] *See* Rule 7.31(h)(2)(B).

becomes the best-priced order on that exchange. For example:

• The Nasdaq Stock Market LLC (''Nasdaq'') Rule 4756(c)(2) provides that Nasdaq transmits for display to the appropriate network processor its best-priced orders. That Rule specifies exceptions of which orders are not transmitted to the SIP, *i.e.,* the reserve size of orders, the discretionary portion of Discretionary Orders, and Non-Displayed Orders. This rule is silent as to whether resting, displayed, depth-of-book orders that have been locked or crossed by another market center and then become the best-ranked orders on Nasdaq are transmitted to the SIP at their original price. Separately, Nasdaq rules provide that certain previously-displayed orders stand their ground. For example, pursuant to Nasdaq Rules 4702(b)(1)(B) and 4702(b)(2)(B), resting ''Price to Comply Orders'' and ''Price to Display Orders'' entered via RASH, QIX, or FIX will stand their ground if locked or crossed by another market center. But these rules discuss top-of-book displayed orders that are crossed, not depth-of-book orders.

• CBOE BZX Exchange, Inc. (''BZX'') Rule 11.12(b) (Priority of Orders) provides that the best-ranked order(s) to buy and the best-ranked order(s) to sell that are displayable in the BZX Book and the aggregated displayed size of such orders associated with such prices shall be collected and made available to quotation vendors for dissemination pursuant to the requirements of Rule 602 of Regulation NMS. This rule is silent as to whether resting, displayed, depth-of-book orders that have been locked or crossed by another market center and then become the best-ranked orders on BZX are transmitted to the SIP at their original price. BZX Rule 11.13(a)(2)(C) (Order Execution and Routing) discusses how orders execute on BZX when the PBBO is crossed, and how that exchange processes incoming orders during a crossed market. But that rule does not address the scenario described above regarding *resting,* displayed, depth-of-book orders and whether they would be made available to quotation vendors for dissemination at their original price, even when the PBBO is crossed. Under Rule 11.13(b)(4), BZX further provides for optional ''Re-Route Instructions'' pursuant to which if a routable order has been locked or crossed by another market, the routable order on the BZX book would be routed to that other market. However, these are optional instructions, which implies that in the absence of one of these instructions, if a routable order on BZX is locked or crossed by another market, such order stands its ground.

• Investors Exchange LLC (''IEX'') Rule 11.240(c)(1) provides that IEX disseminates the aggregate of its best-ranked displayable orders to quotation vendors for dissemination to the SIPs. IEX Rules 11.190(h)(3)(A)(i) and (h)(3)(B)(i) further provide that resting orders that are displayed at a price that later becomes locked or crossed, and were originally displayed in compliance with rules and regulations of IEX, will maintain their displayed price and quantity.[9] While these rules do not distinguish between displayed orders at the top of the IEX book and depth-of-book displayed orders, these rules appear consistent with the Exchange's proposed change to provide that resting, displayed, depth-of-book orders would stand their ground and are eligible to be disseminated to the SIP as the BBO at their original displayed price.

• Long-Term Stock Exchange (''LTSE'') Rule 11.240(c)(1) provides that LTSE disseminates the aggregate of its best-ranked displayable orders to quotation vendors for dissemination to the SIPs.[10] LTSE Rules 11.190(g)(3)(A)(i) and (g)(3)(B)(i) further provide that resting orders that are displayed at a price that later becomes locked or crossed, and were originally displayed in compliance with rules and regulations of LTSE, will maintain their displayed price and quantity.[11] While these rules do not distinguish between displayed orders at the top of the LTSE book and at depth, these rules appear consistent with the Exchange's proposed change to provide that resting, displayed, depth-of-book orders would stand their ground and are eligible to be disseminated to the SIP as the BBO at their original displayed price.

• MEMX LLC (''MEMX'') has filed a Form 1 application for registration as a national securities exchange pursuant to Section 6 of the Act.[12] Proposed MEMX Rule 11.9(b) provides that the best-ranked order(s) to buy and the best-ranked order(s) to sell that are displayable in the MEMX Book and the aggregate displayed size of such orders associated with such prices shall be collected and made available to the SIP. MEMX claims that its proposed MEMX Rule 11.6(j)(1)(A)(ii), which provides that ''[f]ollowing the initial ranking and display or an order subject to the Display-Price Sliding instruction, an order will only be re-ranked and re-displayed to the extent it achieves a more aggressive price, provided, however, that the Exchange will re-rank an order at the same price as the displayed price in the event such orders' displayed price would be a Locking or Crossing Quotation'' makes clear that an order displayed by MEMX would not be re-priced to a less aggressive price if another market locked or crossed an order displayed by MEMX.[13] The Exchange understands this response to mean that MEMX would not re-price displayed orders that were at depth that would become the MEMX best bid or offer.

The Exchange proposes to amend its rules to conform how it reprices orders in this scenario to how other exchanges function. The Exchange believes that because such orders did not lock or cross an Away Market PBBO when they were entered on the Exchange and displayed to the Exchange's proprietary market data, such resting orders have priority at the price at which they were originally displayed.[14] In other words, such resting orders did not cause a locked or crossed market condition.

The Exchange further believes that providing priority to such resting orders on the Exchange Book (*e.g.,* disseminating ''Order A'' as a BB at $10.04 in the above-described scenario) would be consistent with Rule 610(d) under the Act (''Rule 610(d)'').[15] Rule 610(d) provides that ''[e]ach national securities exchange . . . shall establish, maintain, and enforce written rules that . . . are reasonably designed to assure the reconciliation of locked quotations in an NMS stock.'' The proposed rule change is consistent with this requirement because in the scenario described above, the Away Market has published a PBO that crosses not only the Exchange's BB, but also other orders

[9] *See also* Supplementary Material .02 to IEX Rule 11.190(h) (providing that ''[o]rders displayed on the Exchange which were displayed at a price compliant with Regulation NMS are generally permitted to maintain their displayed price in the event an away trading center locks or crosses the price of the IEX displayed order.'')

[10] LTSE has been approved as a registered exchange but is not yet operational.

[11] *See also* Supplementary Material .02 to LTSE Rule 11.190(g).

[12] *See* Securities Exchange Act Release No. 87436 (October 31, 2019), 84 FR 59854 (November 6, 2019) (File No. 1—237). Although MEMX has not yet been approved as an exchange, the Exchange believes that its proposed rules are relevant to this discussion as MEMX expects to be operational in 2020, subject to approval of its Form 1 application.

[13] *See* Letter from Anders Franzon, General Counsel, MEMX, to Ms. Vanessa Countryman, Secretary, Securities and Exchange Commission, dated February 11, 2020, available here: *https://www.sec.gov/comments/10-237/10237-6795399-208386.pdf.*

[14] If the PBBO is locked or crossed at the time of an order's arrival, such arriving orders would be either routed, cancelled, or repriced, as provided for in Rule 7.37(c) (for routable orders) or Rule 7.31(e) (for non-routable orders). This proposed rule change is applicable only to resting orders.

[15] 17 CFR 242.610(d).

that have already been entered on the Exchange and displayed on the Exchange's proprietary market data. Even though such depth-of-book orders have not yet been disseminated to the SIP as part of the Exchange's BBO, those resting orders pre-exist the Away Market quote that crossed them. Therefore, disseminating any pre-existing, displayed orders to the SIP as the new BB at their original price would be consistent with Rule 610(d) because it was the Away Market that crossed previously-displayed orders.

Proposed Rule Change

To effect this proposed rule change, the Exchange proposes to delete Rule 7.31(a)(2)(C) in its entirety. The Exchange also proposes to delete references to this Rule and describe how the Exchange would process orders, as follows.

First, the Exchange proposes several rule changes to specify that previously-displayed orders at any price stand their ground and remain eligible to be quoted or traded at their last-displayed price, even if locked or crossed by an Away Market. The Exchange proposes to specify this principal generally for all displayed orders by amending Rule 7.36(b) to add new subparagraph (4) that would provide that if an Away Market locks or crosses the BBO, the Exchange would not change the display price of any Limit Order ranked Priority 2—Display Orders [16] and any such orders would be eligible to be disseminated as the Exchange's BBO.[17] This proposed rule text both (1) provides specificity that all resting, top-of-book displayed orders stand their ground, which is current functionality,[18] and (2) describes new functionality for previously displayed depth-of-book orders, which would now stand their ground instead of being repriced if they become the Exchange's BBO.

Because such resting orders would no longer be repriced if locked or crossed by an Away Market, such orders would not need to be assigned new working times and would therefore retain priority at their original price. In addition, for market participants that read the Exchange's proprietary market data and are aware of displayed, depth-of-book orders, this proposed change provides greater certainty regarding the price at which a liquidity-taking order would execute on the Exchange.

This proposed rule text therefore promotes transparency and clarity in Exchange rules that all resting, displayed orders, including depth-of-book orders, would stand their ground if locked or crossed by an Away Market. Proposed Rule 7.36(b)(4) is based in part on IEX Rules 11.190(h)(3)(A)(i) and (h)(3)(B)(i) and LTSE Rules 11.190(g)(3)(A)(i) and (g)(3)(B)(i), described above, and is consistent with proposed MEMX Rule 11.6(j)(1)(A)(ii).

The Exchange proposes related changes to remove references to Rule 7.31(a)(2)(C) in connection with Primary Pegged Orders and replace that rule text with proposed new functionality that such orders would stand their ground at their last-displayed price. As described above, if the PBBO becomes locked or crossed, displayed orders on the Exchange would stand their ground. The Exchange proposes that in such scenario, resting Primary Pegged Orders, which are dynamically pegged to the PBBO, would similarly stand their ground. As further proposed, if the PBBO becomes locked or crossed, resting Primary Pegged Orders would wait for a PBBO that is not locked or crossed before the display and working price of such orders is adjusted. While the market is locked or crossed, such orders would remain eligible to trade at their current working price.

To effect these changes, the Exchange proposes to amend Rule 7.31(h)(2)(B) relating to Primary Pegged Orders by deleting the last clause of that Rule [19] and amend the last sentence of that paragraph as follows (new text underlined, proposed text for deletion in brackets): ''If after arrival, the PBBO becomes locked or crossed, the Primary Pegged Order will wait for a PBBO that is not locked or crossed before the *display and* working price [is]*are* adjusted[, but]*and* remains eligible to trade at its current working price.''

Second, the Exchange proposes to specify how the Exchange would process orders following a UTP Regulatory Halt in a UTP Security.[20] Because continuous trading did not precede the resumption of trading of such security on the Exchange, the Exchange does not have a displayed quote eligible to stand its ground. Accordingly, to prevent publishing a quote that would lock or cross an Away Market, the Exchange proposes that before the Exchange publishes a quote, orders that are marketable against a protected quotation on an Away Market would be either routed (if routable) or cancelled (if non-routable).

The second clause of proposed new Rule 7.36(b)(4) would address how the Exchange would process orders before resuming trading and publishing a quote in a UTP Security following a UTP Regulatory Halt. This proposed rule text would be an exception to the first half of the rule text, described above, that previously-displayed orders stand their ground. The Exchange proposes this exception because during a UTP Regulatory Halt, there is no continuous trading and the Exchange ''zeroes'' out its quote, meaning the Exchange removes its BBO from the SIP. However, during a UTP Regulatory Halt, the Exchange may still have orders on its book. Specifically, as set forth in Rule 7.18(b), during a UTP Regulatory Halt, the Exchange cancels resting non-displayed orders and maintains all other resting orders in the Exchange Book at their last working price and display price. The Exchange does not accept new orders during such a halt. As provided for in Rule 7.18(a), the Exchange does not resume trading, including publishing a quote, in such security until it receives notification from the UTP Listing Market that the halt or suspension is no longer in effect and it has received the first Price Band in that security. The Exchange proposes that once it is eligible to resume trading, previously-displayed Limit Orders, *i.e.,* the orders entered before the UTP Regulatory Halt, would be routed (if routable) or cancelled (if non-routable) if such orders would be marketable against protected quotations on Away Markets.

For example, if before a UTP Regulatory Halt in XYZ security, the

[16] As set forth in Rule 7.36(c), all non-marketable orders are ranked and maintained in the Exchange Book in the following manner: (1) Price; (2) priority category; (3) time; and (4) ranking restrictions applicable to an order or modifier condition. Under Rule 7.36(e)(2), ''Priority 2—Display Orders'' are non-marketable Limit Orders with a displayed working price. Limit Orders that are ranked Priority 2—Display Orders can be top of book or at depth.

[17] As set forth in Rule 7.36(b)(1), the Exchange considers an order to be ''displayed'' when it has been disseminated via a market data feed. Because all orders ranked Priority 2—Display Orders, regardless of price, are displayed via proprietary data feeds, such orders are all ''displayed'' for purposes of Exchange rules.

[18] Current Rule 7.31(e)(1)(A)(iii) specifies that Non-Routable Limit Orders stand their ground when crossed by an Away Market PBBO.

[19] The last clause of current Rule 7.31(h)(2)(B) provides: ''provided that, if a resting Limit Order on the Exchange Book is assigned a new display price and working price pursuant to Rule 7.31(a)(2)(C) and the PBBO is still locked or crossed, a resting Primary Pegged Order will also be assigned a new display price and working price pursuant to Rule 7.31(a)(2)(C).''

[20] The term ''UTP Security'' is defined in Rule 1.1(w) to mean a security that is listed on a national securities exchange other than the Exchange and that trades on the Exchange pursuant to unlisted trading privileges and the term ''UTP Regulatory Halt'' is defined in Rule 1.1(y) to mean a trade suspension, halt, or pause caused by the UTP Listing Market in a UTP Security that requires all market centers to halt trading in that security. The term ''UTP Listing Market'' is defined in Rule 1.1(x) to mean the primary listing market for a UTP Security.

Exchange's BBO was $10.10 (100 shares) × $10.12 (100 shares), and before the Exchange resumes trading following that UTP Regulatory Halt, the first PBBO is $10.08 (100 shares) × $10.09 (100 shares), because the Exchange's former best bid of $10.10 is marketable against the new $10.09 PBO, the Exchange would either route that order (if routable) or cancel it (if non-routable). The Exchange would publish the former $10.12 because it is not marketable against an Away Market quotation.

The Exchange believes that following a UTP Regulatory Halt, orders that would lock or cross the Away Market PBBO should either be routed (if routable) or cancelled (if non-routable) if they would be marketable against protected quotations on Away Markets. The Exchange believes that routing or cancelling such orders is consistent with Rule 610(d) because the Away Market does not have an obligation to prevent locking or crossing an Exchange quote in this scenario. Therefore, in this scenario, to prevent locking or crossing the Away Market PBBO, the Exchange would either route or cancel previously-entered orders before publishing a quote.

Third, the Exchange proposes to apply the proposed processing of orders, described above, to odd-lot orders. In other words, odd-lot orders would no longer be processed differently than orders that are a round lot or greater in size. Currently, Rule 7.38(b)(1) and subparagraphs (A)–(C) describe how the working and display price of odd-lot orders are adjusted in relation to the contra-side PBBO. In short, currently, the working and display prices of odd-lot orders are bound by the PBBO, which means that resting odd-lot orders can be repriced if the PBBO changes or becomes locked or crossed.[21]

As proposed, odd-lot sized orders would be priced the same as orders of a round-lot size or higher, and if they are designated Priority 2- Display Orders, they would stand their ground if locked or crossed by an Away Market PBBO. To effect this change, the Exchange proposes to delete Rule 7.38(b)(1) and sub-paragraphs (A)–(C) in their entirety. The Exchange also proposes to delete the clause ''provided that'' at the end of Rule 7.38(b) and make a non-substantive change to that Rule to replace the term ''in'' with the term ''on.'' As a result of these changes, Rule 7.38(b) would provide, without any qualifiers, that ''[r]ound lot, mixed lot and odd-lot orders are treated in the same manner on the Exchange.'' The Exchange proposes an additional non-substantive change to renumber current Rule 7.38(b)(2) as Rule 7.38(c).

Fourth, because displayed odd-lot orders would stand their ground, the Exchange proposes to amend Rule 7.31(d)(1) to add new subparagraph (F) relating to Reserve Orders to specify new functionality of how non-routable Reserve Orders would be replenished if the display quantity of a resting Reserve Order is decremented to an odd-lot size when the PBBO is crossed. The Exchange proposes this change only for non-routable Reserve Orders. These changes are not necessary for a routable Reserve Order because when such order replenishes, the replenish quantity is evaluated for routing to Away Markets and thus would not be displayed at a price that crosses an Away Market.

As proposed in new subparagraph (F) to Rule 7.31(d)(1), if the PBBO is crossed and the display quantity of a Reserve Order to buy (sell) that is a Non-Routable Limit Order is decremented to less than a round lot, the display price and working price of such Reserve Order would not change. This proposed rule text is consistent with the change, described above, that resting displayed orders, including odd-lot sized orders, would stand their ground if crossed by an Away Market. The proposed rule would further provide that the reserve interest that replenishes the display quantity would be assigned a display price one MPV below (above) the PBO (PBB) and a working price equal to the PBO (PBB). Because this is the first time such interest would be displayed, the Exchange proposes to adjust the display and working price so that the replenished quantity would not lock or cross the Away Market, which is the same manner that an arriving Non-Routable Limit Order is priced.[22]

When the PBBO uncrosses, the display price and working price would be adjusted as provided for under paragraph (e)(1) of this Rule relating to Non-Routable Limit Orders.

Fifth, as described above, displayed orders would stand their ground if locked or crossed by an Away Market. However, non-displayed orders do not. As set forth in Rule 7.31(d)(2)(A), the working price of a resting Non-Displayed Limit Order will be adjusted based on the limit price of the order. If the limit price of a Non-Displayed Limit Order to buy (sell) is at or below (above) the PBO (PBB), it will have a working price equal to the limit price. If the limit price of a Non-Displayed Limit Order to buy (sell) is above (below) the PBO (PBB), it will have a working price equal to the PBO (PBB). The Exchange proposes to amend Rule 7.31(d)(1) to provide that the working price of the reserve interest of resting Reserve Orders, which are non-displayed, would be adjusted in the same manner that the working price of Non-Displayed Limit Orders are adjusted.

To effect this change, the Exchange proposes to amend Rule 7.31(d)(1) to add the following sentence: ''The working price of the reserve interest of a resting Reserve Order will be adjusted in the same manner as a Non-Displayed Limit Order, as provided for in paragraph (d)(2)(A) of this Rule.'' The Exchange understands that at least one other exchange also adjusts the price of the non-displayed portion of Reserve Orders in the same manner that such exchange adjusts the price of non-displayed orders.[23]

Together with the proposed rule change described above to Rule 7.36(b), these rule changes make clear that on the Exchange, if crossed by an Away Market PBBO, displayed orders would stand their ground and non-displayed orders, including the reserve interest of resting Reserve Orders, would be repriced based off of the PBBO.

Implementation

Because of the technology changes associated with this proposed rule change, the Exchange will announce the implementation date of this proposed rule change by Trader Update. Subject to effectiveness of this proposed rule

[21] Current Rule 7.38(b)(1) provides that ''[t]he working and display price of an odd lot order will be adjusted both on arrival and when resting on the Exchange Book as follows: (A) If the limit price of an odd lot order to buy (sell) is at or below (above) the PBO (PBB), it will have a working and display price equal to the limit price. (B) If the limit price of an odd lot order to buy (sell) is above (below) the PBO (PBB), it will have a working price equal to the PBO (PBB). The display price will also be adjusted to the PBO (PBB) unless the order's instruction requires a display price that is different from the PBBO. (C) If the PBBO is locked or crossed and the limit price of an odd lot order to buy (sell) is above (below) the PBO (PBB), it will have a working and display price equal to the PBB (PBO). The working and display price of such odd lot order will not be adjusted again until the PBBO unlocks or uncrosses.''

[22] *See* Rule 7.31(e)(1)(A) (describing how arriving Non-Routable Limit Order is priced). On Nasdaq, a Price to Comply Order with Reserve Size replenishes in a similar manner. *See* Nasdaq Rule 4703(h); *see also* Supplementary Material .02 to IEX Rule 11.190(h) (''When a reserve order refreshes its displayed portion, the refreshing shares are not permitted to be displayed at a price that locks or crosses the price of a protected quotation on an away market and are subject to display-price sliding'').

[23] *See* IEX Rule 11.190(b)(2) (stating that the non-displayed portion of reserve orders are treated as non-displayed orders). IEX reprices its non-displayed orders differently from how the Exchange reprices Non-Displayed Limit Orders. *See* IEX Rule 11.190(h)(3)(D). Importantly, both IEX and the Exchange reprice non-displayed when crossed by an Away Market PBBO.

change, the Exchange anticipates that the implementation date will be in the Spring of 2020.

2. Statutory Basis

The Exchange believes that the proposal is consistent with Section 6(b) of the Act,[24] in general, and furthers the objectives of Sections 6(b)(5) of the Act,[25] in particular, because it is 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 mechanisms of, a free and open market and a national market system and, in general, to protect investors and the public interest and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that deleting Rule 7.31(a)(2)(C) and the related proposed amendment to Rule 7.36(b) to add new sub-paragraph (4) would remove impediments to and perfect the mechanism of a free and open market and a national market system because they would promote transparency in Exchange rules that previously-displayed orders would stand their ground if locked or crossed by an Away Market PBBO. The proposed rule changes would further promote transparency because they make clear that resting, displayed, depth-of-book orders that have been locked or crossed by an Away Market PBBO would be eligible to be disseminated to the SIP at their original price if they become the BBO.

The Exchange believes that previously-displayed orders, including depth-of-book orders, have priority at such price and should be able to stand their ground if locked or crossed by an Away Market. The Exchange therefore believes it is consistent with this principle to delete Rule 7.31(a)(2)(C) and change functionality on the Exchange for such orders to stand their ground and not be repriced if another market locks or crosses their price. The proposed change therefore benefits those resting orders because they would be able to keep their original working time and any priority ranking associated with such working time. The proposed change would also benefit liquidity takers, who would have greater certainty regarding the price at which they would receive an execution on the Exchange.

Moreover, the proposed change is consistent with how other exchanges function. While the rules of other exchanges differ in level of detail, these proposed changes are based in part on IEX Rules 11.190(h)(3)(A)(i) and (h)(3)(B)(i)and LTSE Rules 11.190(g)(3)(A)(i) and (g)(3)(B)(i), which similarly provide that previously-displayed orders on those exchanges maintain their display price and quantity if locked or crossed by an another market center. The proposal is also similar to how MEMX proposes it would function if approved as an exchange.

The Exchange further believes that these proposed amendments are consistent with Rule 610(d). If an Away Market publishes a PBBO that crosses not only the Exchange's BBO, but also resting, displayed, depth-of-book orders, it was the Away Market that crossed previously-displayed orders. If such previously-displayed, depth-of-book orders become the Exchange's BBO, the Exchange believes it is appropriate to disseminate those previously-displayed prices and quantities to the SIP as the new BBO because those resting orders pre-existed the Away Market quote that locked or crossed them.

For the same reasons, the Exchange believes that the proposed changes to Primary Pegged Orders would remove impediments to and perfect the mechanism of a free and open market and a national market system because displayed orders that are pegged to a dynamic price would stand their ground at their original displayed price if locked or crossed by an Away Market, which is consistent with the proposed rule change that all displayed orders would stand their ground. These proposed rule changes also promote transparency by specifying that such orders would continue to be eligible to trade at their original working price, and that their display and working prices would not be adjusted until the PBBO is no longer locked or crossed.

The Exchange further believes that routing or cancelling orders that are marketable against an Away Market PBBO following a UTP Regulatory Halt would also remove impediments to and perfect the mechanism of a free and open market and a national market system because in this scenario, the Away Market would not have had an obligation to prevent displaying a locking or crossing quotation. The Exchange proposes to avoid locking or crossing an Away Market PBBO in this scenario by routing or cancelling previously-displayed orders, as applicable. These proposed changes would reduce the number of times resting orders would be repriced, thereby increasing determinism for the price at which orders would be executed on the Exchange.

The Exchange believes that processing odd-lot sized orders in the same manner as round-lot sized orders would remove impediments to and perfect the mechanism of a free and open market because the same principle applies: An order of any size that has been displayed has priority at that price if an Away Market subsequently locks or crosses that price. In addition, the Exchange believes that processing odd-lot orders the same as round-lot sized orders is not novel as it is consistent with the rules of other exchanges.[26]

Finally, the Exchange believes that the proposed changes to Reserve Orders would remove impediments to and perfect the mechanism of a free and open market because it would apply these principles to a Non-Routable Limit Order that is also a Reserve Order. This proposed functionality is also consistent with how Nasdaq and IEX process non-routable orders with reserve interest.[27] The proposed change to reprice the reserve interest of resting Reserve Orders in the same manner as a Non-Displayed Limit Order is priced would also remove impediments to and perfect the mechanism of a free and open market because it would promote consistency in Exchange rules regarding how similar orders are priced when crossed by an Away Market. The proposed change is also consistent with how IEX processes the reserve interest of Reserve Orders.[28]

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[29] the Exchange believes that the proposed rule change would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed change is competitive because it is designed to conform how the Exchange processes previously-displayed orders with the functionality available on other exchanges, *i.e.,* that

[24] 15 U.S.C. 78f(b).

[25] 15 U.S.C. 78f(b)(5).

[26] *See, e.g.,* Nasdaq Rules 4703(b)(3) (defining the term ''odd lot'' as an order attribute) and 4702 (describing which order attributes are available for orders on Nasdaq, without any discussion of odd-lot sized orders being priced differently than round-lot sized orders). *See also* BZX Rules 11.10 (defining the term ''odd lot'') and 11.9 (describing BZX Orders and Modifiers, without any discussion of odd-lot sized orders being priced differently than round-lot sized orders).

[27] *See supra* note 22.

[28] *See supra* note 23.

[29] 15 U.S.C. 78f(b)(8).

such orders would stand their ground if locked or crossed by an Away Market and be eligible to be disseminated to the SIP at their original price. The Exchange believes that the proposed change would promote competition because fewer orders would need to be repriced on the Exchange and therefore liquidity providers seeking for their orders to retain priority may route additional orders to the Exchange. Likewise, liquidity takers may be more likely to route orders to the Exchange if they have greater determinism regarding the price at which their resting, displayed orders on the Exchange would be executed.

Without this proposed rule change regarding how displayed orders would stand their ground if locked or crossed by an Away Market, the Exchange is currently at a competitive disadvantage vis-à-vis all other equity exchanges, which do not reprice orders in this manner. As discussed above, displayed orders on all other equity exchanges, including the two exchanges that recently had their Form 1 applications to be approved as an exchange (IEX and LTSE), stand their ground when locked or crossed by an Away Market and such orders are disseminated to the SIP if they become those exchanges' best bid or offer. In addition, MEMX proposes that displayed orders would stand their ground if locked or crossed by an Away Market.

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 such longer period 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–NYSECHX–2020–06 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–NYSECHX–2020–06. 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 offices 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–NYSECHX–2020–06, and should be submitted on or before April 8, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[30]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–05555 Filed 3–17–20; 8:45 am]

BILLING CODE 8011–01–P

[30] 17 CFR 200.30–3(a)(12).

SOCIAL SECURITY ADMINISTRATION

[Docket No. 2020–0012; Sequence No. 1; OMB Control No. 0960–XXXX]

Information Collection; Improving Customer Experience (OMB Circular A–11, Section 280 Implementation)

AGENCY: Social Security Administration.

ACTION: Notice and request for comments.

SUMMARY: As part of the Administration's commitment to improving customer service delivery, the following proposed Information Collection Request ''Improving Customer Experience (OMB Circular A–11, Section 280 Implementation)'' is pending at the Social Security Administration. The Social Security Administration will submit it to OMB for approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et. seq.*) within 60 days from the date of this notice.

DATES: Submit comments on or before: May 18, 2020.

ADDRESSES: Submit comments identified by Information Collection 0960–XXXX, Improving Customer Experience (OMB Circular A–11, Section 280 Implementation), by any of the following methods:

- *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.
- *Mail:* Social Security Administration, OLCA, 3100 West High Rise, 6401 Security Blvd., Baltimore, MD. ATTN: Reports Clearance Director, Improving Customer Experience (OMB Circular A–11, Section 280 Implementation).

Instructions: Please submit comments only and cite Information Collection 0960–XXXX, Improving Customer Experience (OMB Circular A–11, Section 280 Implementation) in all correspondence related to this collection. To confirm receipt of your comment(s), please check *regulations.gov,* approximately two-to-three business days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

SUPPLEMENTARY INFORMATION:

Title: Improving Customer Experience (OMB Circular A–11, Section 280 Implementation).

Abstract: A modern, streamlined and responsive customer experience means: Raising government-wide customer

experience to the average of the private sector service industry; developing indicators for high-impact Federal programs to monitor progress towards excellent customer experience and mature digital services; and providing the structure (including increasing transparency) and resources to ensure customer experience is a focal point for agency leadership.

This proposed information collection activity provides a means to garner customer and stakeholder feedback in an efficient, timely manner in accordance with the Administration's commitment to improving customer service delivery as discussed in Section 280 of OMB Circular A–11 at *https://www.whitehouse.gov/wp-content/uploads/2018/06/s280.pdf.*

As discussed in OMB guidance, agencies should identify their highest-impact customer journeys (using customer volume, annual program cost, and/or knowledge of customer priority as weighting factors) and select touchpoints/transactions within those journeys to collect feedback.

These results will be used to improve the delivery of Federal services and programs. It will also provide government-wide data on customer experience that can be displayed on *www.performance.gov* to help build transparency and accountability of Federal programs to the customers they serve.

As a general matter, these information collections will not result in any new system of records containing privacy information and will not ask questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

Social Security Administration will only submit collections if they meet the following criteria.

- The collections are voluntary;
- The collections are low-burden for respondents (based on considerations of total burden hours or burden-hours per respondent) and are low-cost for both the respondents and the Federal Government;
- The collections are non-controversial and do not raise issues of concern to other Federal agencies;
- Any collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future;
- Personally identifiable information (PII) is collected only to the extent necessary and is not retained;
- Information gathered is intended to be used for general service improvement and program management purposes; and
- Upon agreement between OMB and the agency all or a subset of information may be released as part of A–11, Section 280 requirements only on *performance.gov*. Summaries of customer research and user testing activities may be included in public-facing customer journey maps.
- Additional release of data must be done coordinated with OMB.

These collections will allow for ongoing, collaborative and actionable communications between the Agency, its customers and stakeholders, and OMB as it monitors agency compliance on Section 280. These responses will inform efforts to improve or maintain the quality of service offered to the public. If this information is not collected, vital feedback from customers and stakeholders on services will be unavailable.

Current Action: New Collection of Information.

Type of Review: New.

Affected Public: Individuals and Households, Businesses and Organizations, State, Local or Tribal Government.

Estimated Number of Respondents: Below is a preliminary estimate of the aggregate burden hours for this new collection. Social Security Administration will provide refined estimates of burden in subsequent notices.

Average Expected Annual Number of Activities: Approximately 17,866,680 customer experience activities such as feedback surveys, focus groups, user testing, and interviews.

Average Number of Respondents per Activity: 1 response per respondent per activity.

Annual Responses: 5,955,560.

Average Minutes per Response: 12 minutes, dependent upon activity.

Note: This burden per response figure is not exact, as we will have multiple collection modalities under this OMB Number with different response time estimates, and we input the closest minute estimate to complete the chart. In the Supporting documents, we will explain in further detail the different modalities and their actual numbers.

Burden Hours: Social Security Administration requests approximately 1,142,192 burden hours.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

All written comments will be available for public inspection at *Regulations.gov*.

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 Office of Management and Budget control number.

Dated: March 13, 2020.

Naomi Sipple,

Reports Clearance Officer, Social Security Administration.

[FR Doc. 2020–05636 Filed 3–17–20; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF STATE

[Public Notice: 11076]

Notice of Determinations; Culturally Significant Objects Imported for Exhibition—Determinations: ''The Paradox of Stillness: Art, Object, and Performance'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects to be included in the exhibition ''The Paradox of Stillness: Art, Object, and Performance,'' imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the

exhibition or display of the exhibit objects at the Walker Art Center, Minneapolis, Minnesota, from on or about April 18, 2020, until on or about July 26, 2020, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Chi D. Tran, Program Administrator, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, and Delegation of Authority No. 236–3 of August 28, 2000.

Marie Therese Porter Royce,

Assistant Secretary, Educational and Cultural Affairs, Department of State.

[FR Doc. 2020–05620 Filed 3–17–20; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

Competitive Funding Opportunity: Accelerating Innovative Mobility (AIM) Challenge Grants

AGENCY: Federal Transit Administration (FTA), U.S. Department of Transportation (DOT).

ACTION: Notice of funding opportunity (NOFO).

SUMMARY: The Federal Transit Administration (FTA) announces the opportunity to apply for $11 million in fiscal year (FY) 2019 research funds for Accelerating Innovative Mobility (AIM) Challenge Grants in the form of cooperative agreements for eligible projects. AIM Challenge Grants are part of FTA's new AIM Initiative to foster innovative transit technologies, practices and solutions that incentivize travelers to choose public transportation, promote economic development in communities, and enhance public/private partnerships to improve personal mobility. FTA will competitively award AIM Challenge Grants for projects that can accelerate the development, implementation and adoption of innovative technologies, practices, and service models to improve mobility and enhance the rider experience, with a focus on innovative service delivery models, creative financing, novel partnerships, and integrated payment solutions.

The AIM Initiative also includes the launch of a national network of innovative transit agencies, or AIM Incubators, to test new mobility solutions and broadly share the results with the public transit industry. AIM Challenge Grant recipients selected through this Notice of Funding Opportunity (NOFO) will be designated as the inaugural class of AIM Incubators.

The FTA may award additional funds, if they are made available to the program prior to the announcement of project selections.

DATES: Complete proposals must be submitted electronically through the *GRANTS.GOV* ''APPLY'' function by 11:59 p.m. Eastern Time on April 17, 2020. Prospective applicants should initiate the process by promptly registering on the *GRANTS.GOV* website to ensure completion of the application process before the submission deadline. Instructions for applying can be found on FTA's website at *http://transit.dot.gov/howtoapply* and in the ''FIND'' module of *GRANTS.GOV.*

The *GRANTS.GOV* funding opportunity ID is FTA–2020–012–TRI–AIM. Mail and fax submissions will not be accepted.

FOR FURTHER INFORMATION CONTACT: Please send any questions regarding this notice to FTA's Research office via email at *AIMChallenge@dot.gov.* For other questions contact Ms. Christina Gikakis, Office of Mobility Innovation, 202–366–2637, or *christina.gikakis@dot.gov.* A Telecommunication Device for the Deaf (TDD) is available for individuals who are deaf or hard of hearing at 202–366–3993. In addition, FTA will post answers to questions and requests for clarifications as well as information about webinars FTA will host to provide further guidance at *www.transit.dot.gov/AIM.*

SUPPLEMENTARY INFORMATION: This notice contains information and instructions relevant to the application process for AIM Challenge Grants. All applicants should read this notice in its entirety to obtain the information needed to submit an eligible and competitive application.

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A. Program Description

Under FTA's Public Transportation Innovation program (49 U.S.C. 5312) FTA may make grants, or enter into contracts or cooperative agreements, for research, development, demonstration and deployment projects of national significance to public transportation agencies that the Secretary determines will improve public transportation service. The AIM Challenge Grants has been developed under this authority.

The AIM Challenge Grants are part of FTA's new AIM Initiative to foster innovative transit technologies, practices and solutions that incentivize travelers to choose public transportation, promote economic development in communities, and enhance public/private partnerships to improve personal mobility. Further, the AIM Initiative seeks to ensure these new technologies or practices permit interoperability across systems and modes. The AIM Initiative also seeks to harness Federal, local and private sector investments in transportation and mobility innovations. The FTA, in collaboration with the public transportation industry, has invested significant resources in advancing the state of the practice as well as developing and demonstrating technologies and practices to make public transportation safer, more effective and efficient. The transportation sector and rider expectations have evolved, with more options and capabilities now available.

The FTA seeks applications for AIM Challenge Grant projects from public transportation-led teams that can accelerate the development and adoption of innovative technologies, practices, and service models to improve mobility and enhance the rider experience, with a focus on innovative service delivery models, creative financing, novel partnerships, and integrated payment solutions. AIM Challenge Grant recipients selected through this NOFO will be designated as the inaugural class of AIM Incubators, a national network of innovative transit agencies that test new mobility solutions and broadly share the results with industry. The FTA provides this funding opportunity based on the traditional challenge grant concept of

achieving specific innovation goals and using that achievement to spotlight a grantee (*i.e.,* AIM Incubators) and disseminate proven innovative mobility practice(s) in the public transportation industry.

To that end, the goals of the AIM Challenge Grants are to:

- Explore and validate forward-thinking approaches to improve transit system design, service, and financing.
- Provide funding to transit agencies in all types of communities—urban, suburban, rural—to identify, test, and prove out new approaches, technologies and service models.
- Establish a national network of public transportation stakeholders that are incorporating innovative approaches and business models to improve mobility and that will share their project results.
- Identify and promote the most promising and effective innovations that can be implemented more broadly through FTA's capital programs.

The AIM Challenge Grants emphasize the Department's commitment to mobility innovation for all communities by incorporating principles of DOT's new Rural Opportunities to Use Transportation for Economic Success (R.O.U.T.E.S.) initiative. A strong transportation network is critical to the functioning and growth of the American economy. The nation's industry depends on the transportation network to move the goods that it produces, and facilitate the movements of the workers who are responsible for that production. When the nation's highways, railways, and ports function well, that infrastructure connects people to jobs, increases the efficiency of delivering goods and thereby cuts the costs of doing business, reduces the burden of commuting, and improves overall well-being.

Rural transportation networks play a vital role in supporting our national economic vitality. Addressing the deteriorating conditions and disproportionately high fatality rates on our rural transportation infrastructure is of critical interest to the Department, as rural transportation networks face unique challenges in safety, infrastructure condition, and passenger and freight usage. Consistent with the R.O.U.T.E.S. Initiative, FTA encourages applicants to consider how the project will address the challenges faced by rural areas.

The FTA will seek to fund multiple AIM Challenge Grant projects that are aligned with the following key underlying principles:

- Test innovative technologies, practices, approaches, or service models that can produce outcomes and knowledge of national significance and advance the state of the practice for public transportation in the U.S.
- Create a portfolio of projects that consider the needs of different types of communities and advance technology innovations, practices and/or partnership models that resonate and are adoptable by all transit agencies, including those that serve rural areas.
- Leverage private sector innovation to improve mobility through novel public private partnerships.
- Advance robust, replicable transit-led business models, and sustainable public private partnerships that enable expanded opportunities for innovation beyond the AIM Challenge Grants.
- Support the concept of the complete trip to ensure all travelers benefit from improved mobility regardless of their location, age, income, or abilities.

B. Federal Award Information

This notice makes available $11 million under the Public Transportation Innovation Program, 49 U.S.C. 5312(b), to support the research, development, demonstration, and deployment and evaluation of research and technology of national significance to transit, that the Secretary of Transportation determines will improve public transportation.

There is no minimum or maximum grant award amount. Only proposals from eligible recipients for eligible activities will be considered for funding. Due to funding limitations, proposers that are selected for funding may receive less than the amount originally requested. In those cases, applicants must be able to demonstrate that the proposed project is still viable and can be completed with the amount awarded.

Project recipients selected for funding under AIM Challenge Grants also will be designated as AIM Incubators. Applicants may use no more than $50,000 of the Federal project funds awarded as part of their AIM Challenge Grant to support AIM incubator activities, such as peer outreach and knowledge transfer.

Recipients of the previous FTA mobility innovations demonstration programs, including Integrated Mobility Innovation (IMI) and Mobility on Demand (MOD) Sandbox demonstrations recipients, may apply for funding for additional projects. As FTA is seeking to promote new innovative service models to increase the efficiency and effectiveness of transit, applicants should demonstrate the extent to which the newly proposed project is indeed a new effort. If the proposed project is a continuation of a prior project, the applicant should describe how the concept has evolved since it was first implemented.

Funds under this notice cannot be used to reimburse recipients for otherwise eligible expenses incurred prior to FTA award of a Grant Agreement or Cooperative Agreement unless FTA has issued pre-award authority for selected projects. AIM Challenge Grant projects are research and development efforts and, as such, FTA Research Circular 6100.1E (available at *www.transit.dot.gov/regulations-and-guidance/fta-circulars/research-technical-assistance-and-training-program*) rules will apply in administering the program.

C. Eligibility Information

To be selected for the AIM Challenge Grants, an applicant must be an Eligible Applicant and the project must be an Eligible Project as defined below.

1. Eligible Applicants

Eligible applicants under this notice are providers of public transportation, including public transportation agencies, state/local government DOTs, and federally recognized Indian tribes. Eligible applicants may identify one or more strategic project partner(s) with a substantial interest and involvement in the project. Applications must clearly identify the eligible applicant and all project partners on the project team.

Eligible project partners under this program may include, but are not limited to:

- Private for-profit and not-for-profit organizations, including shared-use mobility providers, technology system suppliers and integrators, automated vehicle technology providers, property managers and developers, and others;
- private operators of transportation services, such as employee shuttle services, airport connector services, university transportation systems, or parking and tolling or airports authorities;
- other operators of public transportation, including public transportation agencies, State/local government DOTs, and Federally recognized Indian tribes.
- bus or vehicle manufacturers or suppliers;
- banking or financial institutions;
- State or local government entities, including multi-jurisdictional partnerships, and organizations such as a Metropolitan Planning Organization; or
- other organizations including research consortia or not-for-profit industry organizations, institutions of higher education, and others.

The project team should include all project partners necessary to successfully carry out the prospective project, and be structured to best leverage Federal funds.

The applicant must be able to carry out the proposed agreement and procurements, if needed, with project partners in compliance with all applicable Federal, State, and local laws.

Key partners can be designated by applicants that share the costs, risks, and rewards of early deployment, demonstration and operation of innovative projects. The FTA also may determine that any identified project partner in the proposal is a key partner and make any award conditional upon the participation of that key partner. A key partner is essential to the project as approved by FTA and, therefore, is eligible for a noncompetitive award by the applicant to provide the goods or services described in the application. The applicant must clearly indicate whether each partner is a key partner. A key partner's participation on a selected project may not be substituted later without FTA's approval.

To be considered eligible, applicants must be able to demonstrate the requisite legal, financial, and technical capabilities to receive and administer Federal funds under this program.

2. Cost Sharing or Matching

The Federal share of project costs under this program is limited to 80 percent. Applicants may seek a lower Federal contribution. The applicant must provide the local share of the net project cost in cash, or in-kind, and must document in its application the source of the local match. Eligible sources of local match are detailed in FTA Research Circular 6100.1E. (available at *www.transit.dot.gov/regulations-and-guidance/fta-circulars/research-technical-assistance-and-training-program*).

3. Eligible Projects

This notice solicits applications for AIM Challenge Grant projects that demonstrate innovative technologies, applications, practices, and/or service models that can lead to more efficient public transportation service, better mobility for individuals, and enhance the overall rider experience, with special emphases on innovative service delivery models, creative financing, novel partnerships and integrated payment solutions. Applicants are also encouraged to submit applications with other innovative models and ideas that may not fall into one of these areas.

To help shape AIM Challenge Grants, the following list provides some examples of innovative technologies, practices and solutions for consideration. Please note that the list is provided for examples only, and not meant to be exhaustive or prescriptive.

- Integrated scheduling, reservation, and payments across all mobility providers in a region.
- Innovative dynamic mobility hubs in rural areas.
- Innovative data tools to predict movement of all travelers on a transportation network to target transit services and provide more comprehensive traveler information.
- New operational models of bus service that are more flexible, better integrated into the community, and more appealing.
- Emerging approaches or technologies that enable access for all populations to take advantage of mobility advances, including older Americans, school-aged populations traveling independently, and persons with disabilities.
- Innovative projects to demonstrate market-ready or near market-ready transit automation for revenue service.
- Novel partnerships with private, public, or nonprofit entities that connect riders to high-demand services or destinations.

Eligible activities include all activities leading to the development and testing of innovative mobility, such as planning and developing business models, obtaining equipment and service, acquiring or developing software and hardware interfaces to implement the project, operating or implementing the new service model, and evaluating project results. Transit agencies selected for AIM Challenge Grants awards will be designated as AIM Incubators, and will serve as experts and provide support to other agencies seeking to improve transit service and mobility in their communities, through activities such as peer exchanges and knowledge sharing. AIM Incubator activities are eligible and required activities under the AIM Challenge Grants up to the funding previously established.

4. Project Timelines

Projects funded under the AIM Challenge Grants will be allowed a maximum of 12 months for project planning. Project innovations or demonstration of new business models should be fully launched within 12 months of award.

D. Application and Submission Information

1. Address To Request Application Package

Instructions for applying can be found on the FTA website at *http://transit.dot.gov/howtoapply.* Applications must be submitted electronically through *GRANTS.GOV.* General information for submitting applications through *GRANTS.GOV* can be found at *www.transit.dot.gov/howtoapply* along with specific instructions for the forms and attachments required for submission. Mail and fax submissions will not be accepted.

2. Content and Form of Application Submission

Addressing the deteriorating conditions and disproportionately high fatality rates on our rural transportation infrastructure is of critical interest to the Department, as rural transportation networks face unique challenges in safety, infrastructure condition, and passenger and freight usage. Consistent with the R.O.U.T.E.S. Initiative, the Department will consider how the project will address the challenges faced by rural areas.

A complete proposal submission consists of two forms: the SF–424 Application for Federal Assistance (available at *GRANTS.GOV*) and the supplemental form for the 2020 AIM Challenge Grants (downloaded from *GRANTS.GOV* or the FTA website at *www.transit.dot.gov/AIM*).

A complete application must include responses to all sections of the SF–424 Application for Federal Assistance and the supplemental form. The information on the supplemental form will be used to determine applicant and project eligibility for the program, and to evaluate the proposal against the selection criteria described in part E of this notice. Applicants may attach additional supporting information to the SF–424 submission, including but not limited to letters of support, project budgets, or excerpts from relevant planning documents. Supporting documentation must be described and referenced by file name in the appropriate response section of the supplemental form, or it may not be reviewed.

Information such as applicant name, Federal amount requested, local match amount, description of areas served, etc., may be requested in varying degrees of detail on both the SF–424 form and supplemental form. An applicant must fill in all fields unless stated otherwise on the forms. If

copying information into the supplemental form from another source, the applicant should verify that the supplemental form has fully captured pasted text and that it has not truncated the text due to character limits built into the form. An applicant should use both the ''Check Package for Errors'' and the ''Validate Form'' validation buttons on both forms to check all required fields on the forms. An applicant should also ensure that the Federal and local amounts specified are consistent throughout the application.

The SF–424 Mandatory Form and the supplemental form will prompt applicants for the required information, including:

a. Applicant name.
b. Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number.
c. Key contact information (including contact name, address, email address, and phone).
d. Congressional district(s) where project will take place.
e. Project information (including title, an executive summary, and type).
f. Information on areas served by project (*i.e.,* indicate urban, rural, or both) including current state of public transportation and mobility in the area served.
g. A description of the need for the project (research need or opportunity project addresses).
h. A description of all innovative technologies, practices or business models proposed as part of the project scope.
i. Evidence on how the project will support the AIM Challenge Grants goals and underlying principles as described in Section A of this NOFO ''Program Description,'' and the overall significance of the project to advancing mobility innovation.
j. A description of how the proposed project would address the unique challenges facing rural transportation networks, regardless of the geographic location of those activities.
k. Details on any partners, their roles and anticipated contributions. Indicate which partners are ''key partners'' essential to the success of the proposed project. Indicate which partners provided letter of commitment that are attached to the application.
l. A description of the overall project implementation strategy.
m. A description of how the applicant will fulfill the role of AIM Incubator, and activities that it will undertake.
n. A description of how the project will be evaluated and any details on the types of data that will be generated and how the project team will provide access for FTA or its designee to this project-related data for purposes of evaluation.
o. Project budget.
p. Project timeline.
q. Evidence that the applicant can provide the local cost share.
r. A description of the technical, legal and financial capacity of the applicant, and team members to successfully implement project.
s. An explanation of the scalability of the project.
t. Whether the project impacts an Opportunity Zone, designated pursuant to 26 U.S.C. 1400Z–1.

3. Unique Entity Identifier and System for Award Management (SAM)

Each applicant is required to: (1) Be registered in SAM before submitting an application; (2) provide a valid unique entity identifier in its application; and (3) continue to maintain an active SAM registration with current information at all times during which the applicant has an active Federal award or an application or plan under consideration by FTA. These requirements do not apply if the applicant has an exemption approved by FTA under Federal grants and agreements Uniform Guidance (2 CFR 25.110(d)). FTA may not make an award until the applicant has complied with all applicable unique entity identifier and SAM requirements. If an applicant has not fully complied with the requirements by the time FTA is ready to make an award, FTA may determine that the applicant is not qualified to receive an award and use that determination as a basis for making a Federal award to another applicant. All applicants must provide a unique entity identifier provided by SAM. SAM registration takes approximately 3–5 business days, but FTA recommends allowing ample time, up to several weeks, for completion of all steps. For additional information on obtaining a unique entity identifier, please visit *www.sam.gov.*

4. Submission Dates and Times

Project proposals must be submitted electronically through *GRANTS.GOV* by 11:59 p.m. Eastern Time on April 17, 2020. Mail and fax submissions will not be accepted. FTA urges applicants to submit applications at least 72 hours prior to the due date to allow time to correct any problems that may have caused either *GRANTS.GOV* or FTA systems to reject the submission. Proposals submitted after the deadline will only be considered under extraordinary circumstances not under the applicant's control. Deadlines will not be extended due to scheduled website maintenance. *GRANTS.GOV* scheduled maintenance and outage times are announced on the *GRANTS.GOV* website.

Within 48 hours after submitting an electronic application, the applicant should receive an email message from *GRANTS.GOV* with confirmation of successful transmission to *GRANTS.GOV*. If a notice of failed validation or incomplete materials is received, the applicant must address the reason for the failed validation, as described in the email notice, and resubmit before the submission deadline. If making a resubmission for any reason, applicants must include all original attachments regardless of which attachments were updated and check the box on the supplemental form indicating this is a resubmission.

Applicants are encouraged to begin the process of registration on the *GRANTS.GOV* site well in advance of the submission deadline. Registration is a multi-step process, which may take several weeks to complete before an application can be submitted. Registered applicants may still be required to take steps to keep their registration up to date before submissions can be made successfully: (1) Registration in the System for Award Management (SAM) is renewed annually; and, (2) persons making submissions on behalf of the Authorized Organization Representative (AOR) must be authorized in *GRANTS.GOV* by the AOR to make submissions.

5. Funding Restrictions

Funds under this NOFO cannot be used to reimburse applicants for otherwise eligible expenses incurred prior to FTA award of a grant agreement until FTA has issued pre-award authority for selected projects.

6. Other Submission Requirements

The FTA encourages applicants to identify scaled funding options in case insufficient funding is available to fund a project at the full requested amount. If an applicant indicates that a project is scalable, the applicant must provide an appropriate minimum funding amount that will fund an eligible project that achieves the objectives of the program and meets all relevant program requirements. The applicant must provide a clear explanation of how a reduced reward would affect the project budget. The FTA may award a lesser amount regardless of whether the applicant provides a scalable option.

E. Application Review Information

The FTA will evaluate project proposals for AIM Challenge Grants based on the criteria described in this notice. Projects will be evaluated primarily on the responses provided in the supplemental form. Additional information may be provided to support the responses; however, any additional documentation must be directly referenced on the supplemental form,

including the file name where the additional information can be found.

1. Criteria

Project proposals will be evaluated by FTA per the following six selection criteria. FTA strongly encourages each applicant to demonstrate the responsiveness of a project to all criteria shown below with the most relevant information that the applicant can provide. The selection criteria are as follows:

a. Demonstration of Innovation

The FTA is seeking projects that address innovation related to exploring and testing new technologies, practices, approaches or business models for public transportation that can lead to greater operational efficiency, greater personal mobility, more efficient operations, or insights into new system design, service, financing or partnering mechanisms. Projects should clearly identify a specific innovative premise which serves a need, the proposed project approach to addressing the need, and how the proposed project will provide outcomes or new insights that expand the public transportation industry's understanding of new mobility innovations. The FTA will assess the extent to which the applicant uses innovative strategies, including (i) innovative technologies, (ii) innovative financing, and/or (iii) innovative operations and identifies specific needs in the area of mobility innovation that can produce outcomes and knowledge of national significance and advance the state of the practice for public transportation in the U.S.

b. Demonstration of Benefit

The application should demonstrate the utility of the proposed project to accelerate the transit industry's ability to implement new technologies, operational innovations, approaches or service models that support FTA's AIM Challenge Grants goals, and are consistent with the AIM Challenge Grants guiding principles, as detailed in this NOFO.

The FTA will evaluate proposals based on their capacity to accelerate the development and adoption of innovative technologies, practices, and service models to improve mobility and enhance the rider experience. There will be a focus on innovative service delivery models, creative financing, novel partnerships, and integrated payment solutions.

The FTA will consider the extent to which each proposal explores innovative technologies, practices, approaches or service models that produce outcomes and knowledge of national significance and advance the state of the practice for public transportation in the U.S; advances technologies, innovations, practices or partnership models that resonate with all transit agencies, including those in rural areas; leverages private sector innovation; advances robust, replicable business models, and sustainable public private partnerships; and ensures that all travelers benefit from enhanced mobility regardless of location, age, income, or abilities.

c. Planning and Partnerships

For applications that include project partners, applicants must detail all project partners and their specific role. The FTA will evaluate the extent to which the project contains strong, cohesive partnerships and the collaboration necessary to successfully implement the proposed project. Applications should describe how project partners plan to work collaboratively and should show evidence of strong commitment and cooperation among project partners through letters of support or agreements among the partners. Applications should describe how partners will participate in each aspect of project planning, implementation and evaluation. The FTA also will evaluate the experience, capacity, and demonstrated partnership commitment of the named project partners as pertains to successful implementation of the proposed project. Applicants are advised to submit information on the partners' qualifications and experience as a part of the application, and documentation of their commitment to the project.

Any project partner can be designated by the applicant as a key partner that shares the costs, risks, and rewards of early deployment and demonstration of innovation. The applicant must explicitly indicate whether each partner is a key partner. A key partner's participation on a selected project may not be substituted later without FTA's approval. Entities who are involved in the project but not named in the application will be required to be selected through a competitive procurement.

d. Local Financial Commitment

The FTA will fund up to 80 percent of the net project cost; a local share of at least 20 percent of the net project cost is required. Applicants must identify the source of the local cost share and describe whether such funds are currently available for the project or will need to be secured if the project is selected for funding. The FTA will consider the availability of the local cost share as evidence of local financial commitment to the project. Additional consideration will be given to those projects for which local funds have already been made available or reserved. Applicants should submit evidence of the availability of funds for the project, for example by including a board resolution, letter of support from the State or other documentation of the source of local funds such as a budget document highlighting the line item or section committing funds to the proposed project. In addition, as evidence of local financial commitment, an applicant may propose a local cost share that is greater than the minimum requirement.

e. Project Implementation Strategy

Projects will be evaluated based on the extent to which the project is ready to start within a reasonable period of time and whether the applicant's proposed implementation plans are reasonable and complete, with project innovations or demonstration of new business models fully launched within 12 months of award.

In assessing whether the proposed implementation plans are reasonable and complete, FTA will review the proposed project implementation plan, including all necessary project milestones and the overall project timeline. The FTA will consider if the project's implementation strategy addresses how the project will support FTA's independent project evaluation efforts, data access and sharing of project results, project evaluation against mobility-specific metrics, and the AIM Incubator efforts.

For projects that will require formal coordination, approvals or permits from other agencies or project partners, the applicant must demonstrate coordination with these organizations and their support for the project, such as through letters of support. The FTA also will consider the risks to project implementation, and the extent to which the project implementation strategy addresses these risks.

f. Technical, Legal, and Financial Capacity

The FTA will evaluate proposals on the capacity of the lead agency and any partners to successfully execute the project. The FTA may review relevant oversight assessments and records to determine whether there are any outstanding legal, technical or financial issues with the applicant that would affect the outcome of the proposed project. Applicants with outstanding

legal, technical or financial compliance issues from an FTA compliance review or Federal Transit grant-related Single Audit finding must explain how corrective actions taken will mitigate negative impacts on the proposed project.

For applications that include named project partners, FTA will also consider the technical, legal and financial capacity of the partner to successfully implement the proposed project. Applicants are advised to submit information on the partners' qualifications and experience as a part of the application.

2. Review and Selection Process

A technical evaluation panel comprising FTA and other Departmental and/or Federal agency staff will review project proposals against the selection criteria listed above. The technical evaluation committee may seek clarification from any applicant about any statement made in a proposal. The FTA also may request additional documentation or information to be considered during the evaluation process. After the evaluation of all eligible proposals, the technical evaluation committee will provide project recommendations to the FTA Administrator. The FTA Administrator will determine the final list of project selections, and the amount of funding for each project. Geographic diversity, diversity of project type, the applicant's receipt of other Federal funding, and projects located in or that support public transportation service in a qualified opportunity zone designated pursuant to 26 U.S.C. 1400Z–1 may be considered in FTA's award decisions. The FTA may prioritize projects proposed with a higher local share.

In addition to the criteria and considerations outlined in this section, the FTA Administrator will consider the following key Departmental objectives:

- Supporting economic vitality at the national and regional level;
- Leveraging Federal funding to attract other, non-federal sources of investment, including value capture;
- Using innovative approaches to improve safety and expedite project delivery; and,
- Holding grant recipients accountable for their performance and achieving specific, measurable outcomes identified by grant applicants.

Addressing the deteriorating conditions and disproportionately high fatality rates on our rural transportation infrastructure is of critical interest to the Department, as rural transportation networks face unique challenges in safety, infrastructure condition, and passenger and freight usage. Consistent with the R.O.U.T.E.S. Initiative, the Department will consider how the project will address the challenges faced by rural areas.

Prior to making an award, FTA is required to review and consider any information about the applicant that is in the Federal Awardee Performance and Integrity Information Systems accessible through SAM. An applicant may review and comment on information about itself that a Federal awarding agency previously entered. FTA may consider any comments by the applicant, in addition to the other information in the designated integrity and performance system, in making a judgment about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in the Office of Management and Budget's Uniform Requirements for Federal Awards (2 CFR 200.205).

F. Federal Award Administration Information

1. Federal Award Notice

The FTA Administrator will announce the final project selections on the FTA website. At the time the project selections are announced, FTA may extend pre-award authority for the selected projects. There is no blanket pre-award authority for the selected projects before announcement.

2. Administrative and National Policy Requirements

a. Pre-Award Authority

The FTA will issue specific guidance to recipients regarding pre-award authority at the time of selection. FTA does not provide pre-award authority for discretionary funds until projects are selected, and even then, there are Federal requirements that must be met before reimbursable costs are incurred. For more information about FTA's policy on pre-award authority, please see the FY 2019 Apportionment Notice published on July 3, 2019 which can be accessed at *www.govinfo.gov/content/pkg/FR-2019-07-03/pdf/2019-14248.pdf.*

b. Grant Requirements

If selected, awardees will apply for a cooperative agreement through FTA's Transit Award Management System (TrAMS). All recipients must follow the requirements of FTA Research Circular 6100.1E. Technical assistance regarding these requirements is available from FTA.

c. Buy America

Federal transit law requires that all capital procurements meet Buy America requirements, which require that all iron, steel, or manufactured products be produced in the U.S., unless a waiver is granted. These requirements help create and protect manufacturing jobs in the U.S. The Fixing America's Surface Transportation (FAST) Act (Pub. L. 114–94, Dec. 4, 2015) amended the Buy America requirements to provide for a phased increase in the domestic content for rolling stock. For FY 2020 and beyond, the cost of rolling stock components and subcomponents produced in the United States must be more than 70 percent of the cost of all components. There is no change to the requirement that final assembly of rolling stock must occur in the United States. The FTA issued guidance on the implementation of the phased increase in rolling stock domestic content on September 1, 2016. A copy of the policy guidance may be found in 81 FR 60278 (September 1, 2016), *www.govinfo.gov/content/pkg/FR-2016-09-01/pdf/2016-21007.pdf.* Information for other, non-rolling stock, capital procurements is available on FTA's website *www.transit.dot.gov/buyamerica.* Any proposal that will require a waiver must identify the items for which a waiver will be sought in the application. Applicants should not proceed with the expectation that waivers will be granted, nor should applicants assume that selection of a project under the AIM Initiative that includes a partnership with a manufacturer, vendor, consultant, or other third party constitutes a waiver of the Buy America requirements applicable at the time the project is undertaken.

d. Disadvantaged Business Enterprise

The FTA requires that its recipients receiving planning, capital and/or operating assistance that will award prime contracts exceeding $250,000 in FTA funds in a Federal fiscal year comply with the Disadvantaged Business Enterprise (DBE) program regulations at 49 CFR part 26. Applicants should expect to include any funds awarded, excluding those to be used for vehicle procurements, in setting their overall DBE goal. Note, however, that projects including vehicle procurements remain subject to the DBE program regulations. The rule requires that, prior to bidding on any FTA-assisted vehicle procurement, entities that manufacture vehicles, or perform post-production alterations or retrofitting must submit a DBE Program plan and goal methodology to FTA.

Further, to the extent that a vehicle remanufacturer is responding to a solicitation for new or remanufactured vehicles with a vehicle to which the remanufacturer has provided post-production alterations or retro-fitting (*e.g.,* replacing major components such as an engine to provide a ''like new'' vehicle), the vehicle remanufacturer is considered a transit vehicle manufacturer and must also comply with the DBE regulations.

Grant recipients must verify each manufacturer's compliance with these requirements before accepting its bid. A list of compliant, certified transit vehicle manufacturers (TVMs) is posted on FTA's web page at *www.fta.dot.gov/regulations-and-guidance/civil-rights-ada/eligible-tvms-list.* Please note that this list is nonexclusive and recipients must contact FTA before accepting bids from entities not listed on this web-posting. Recipients may also establish project specific DBE goals for vehicle procurements. FTA will provide additional guidance as grants are awarded. For more information on DBE requirements, please contact Monica McCallum, Office of Civil Rights, 206–220–7519, email: *monica.mccallum@dot.gov.*

e. Standard Assurances

The applicant assures that it will comply with all applicable Federal statutes, regulations, executive orders, directives, FTA circulars, and other Federal administrative requirements in carrying out any project supported by the FTA grant. The applicant acknowledges that it is under a continuing obligation to comply with the terms and conditions of the grant agreement issued for its project with FTA. The applicant understands that Federal laws, regulations, policies, and administrative practices might be modified from time to time and may affect the implementation of the project. The applicant agrees that the most recent Federal requirements will apply to the project, unless FTA issues a written determination otherwise. The applicant must submit the Certifications and Assurances before receiving a grant if it does not have current certifications on file.

3. Other National Policy Requirements

a. Independent Evaluation

Projects funded under this announcement will be subject to evaluation by an independent evaluator selected by FTA. Recipients will be required to coordinate with the independent evaluator to assist in developing an evaluation plan and collecting, storing and managing data required to fulfill that evaluation plan.

b. Draft Mobility Metrics

Projects funded under this notice will be required to support the efforts of FTA or its designee to evaluate the project and its outcomes against mobility-specific metrics. FTA will work with the project team to implement evaluation plans that are consistent with FTA's draft models for Mobility Metrics.

c. Data Access and Data Sharing

All work conducted under the AIM Challenge Grants should make every attempt to follow USDOT data policies outlined in the DOT Public Access Plan (*www.transportation.gov/mission/open/official-dot-public-access-plan-v11*).

d. AIM Incubators and Knowledge Transfer

The AIM Initiative also includes efforts to launch a national network of innovative transit agencies, or AIM Incubators, to test new mobility solutions and share the results broadly with industry. AIM Challenge Grant recipients selected through this NOFO will be designated as the inaugural class of AIM Incubators. They will work through the FTA technical assistance program and provide ongoing outreach. Applicants selected for project awards must be willing to share project outcomes and methods with FTA and the larger public transportation community. Recipients may be asked to participate in information exchange meetings, webinars, or outreach events to support FTA's goal of advancing mobility innovations. Applicants should allocate a portion of their budgets, up to $50,000 of the Federal project budget, to support their work as AIM Incubators, which may include travel or presentations at key industry gatherings, peer exchanges and similar knowledge transfer activities.

4. Reporting

Post awards reporting requirements include electronic submission of Federal Financial Reports and Milestone Progress Reports in FTA's electronic grants management system.

G. Federal Awarding Agency Contacts

For further information concerning this notice, contact FTA Research office via email at *AIMChallenge@dot.gov,* or please contact Ms. Christina Gikakis, Office of Mobility Innovation, 202–366–2637, or *christina.gikakis@dot.gov.* A TDD is available for individuals who are deaf or hard of hearing at 202–366–3993. In addition, FTA will post answers to questions and requests for clarifications as well as information about webinars for further guidance at *www.transit.dot.gov/AIM.* To ensure applicants receive accurate information about eligibility or the program, the applicant is encouraged to contact FTA directly, rather than through intermediaries or third parties, with questions.

K. Jane Williams,

Acting Administrator.

[FR Doc. 2020–05611 Filed 3–17–20; 8:45 am]

BILLING CODE 4910–57–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2020–0050]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel FRIVOLOUS (Motor Vessel); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before April 17, 2020.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2020–0050 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2020–0050 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2020–0050, 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.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if

we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel FRIVOLOUS is:

—*Intended Commercial Use of Vessel:* ''Time Charters''
—*Geographic Region Including Base of Operations:* ''Florida, New York (excluding New York Harbor), Connecticut, Rhode Island And Massachusetts'' (Base of Operations: Miami Beach, FL)
—*Vessel Length and Type:* 68′ motor vessel

The complete application is available for review identified in the DOT docket as MARAD–2020–0050 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov,* keyword search MARAD–2020–0050 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

* * * * *

Dated: March 12, 2020.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2020–05542 Filed 3–17–20; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2020–0051]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel POINT OF ARIES (Motor Vessel); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before April 17, 2020.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2020–0051 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2020–0051 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2020–0051, 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.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey

Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel POINT OF ARIES is:

—*Intended Commercial Use of Vessel:* ''Small group private tours and outings on the San Francisco Bay. Boat operated by an appropriately licensed captain. Some use for oceanographic and marine related research''

—*Geographic Region Including Base of Operations:* ''California'' (Base of Operations: Point Richmond, CA)

—*Vessel Length and Type:* 36′ motor vessel

The complete application is available for review identified in the DOT docket as MARAD–2020–0051 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov.,* keyword search MARAD–2020–0051 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

* * * * *

Dated: March 12, 2020.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2020–05543 Filed 3–17–20; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2020–0052]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel PRONTO (Motor Vessel); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before April 17, 2020.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2020–0052 by any one of the following methods:

• *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2020–0052 and follow the instructions for submitting comments.

• *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2020–0052, 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.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel PRONTO is:

—*Intended Commercial Use of Vessel:* ''To carry passengers only''

—*Geographic Region Including Base of Operations:* ''Florida, Georgia, South Carolina, North Carolina, Virginia,

Maryland, Washington DC, Delaware, New Jersey, New York, Connecticut, Rhode Island, Massachusetts, New Hampshire, Maine'' (Base of Operations: Sag Harbor, NY)

—*Vessel Length and Type:* 88′ motor vessel

The complete application is available for review identified in the DOT docket as MARAD–2020–0052 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov.,* keyword search MARAD–2020–0052 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

* * * * *

Dated: March 12, 2020.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2020–05544 Filed 3–17–20; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2020–0053]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel CRUZAN RHUMB II (Catamaran); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before April 17, 2020.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2020–0053 by any one of the following methods:

• *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2020–0053 and follow the instructions for submitting comments.

• *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2020–0053, 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.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel CRUZAN RHUMB II is:

—*Intended Commercial use of Vessel:* ''Sunset sail trips (approx 2–3 hours in length)''

—*Geographic Region Including Base of Operations:* ''Florida'' (Base of Operations: Key West, FL)

—*Vessel Length and Type:* 39′ catamaran.

The complete application is available for review identified in the DOT docket as MARAD–2020–0053 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag

vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov,* keyword search MARAD–2020–0053 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

* * * * *

Dated: March 12, 2020.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2020–05541 Filed 3–17–20; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2020–0054]

Request for Comments of a Previously Approved Information Collection

AGENCY: Maritime Administration, DOT.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, this notice announces that the Information Collection Request (ICR) abstracted below is being forwarded to the Office of Management and Budget (OMB) for review and comments. A **Federal Register** Notice with a 60-day comment period soliciting comments on the following information collection was published on December 26, 2019.

DATES: Comments must be submitted on or before April 17, 2020.

ADDRESSES: Send comments regarding the burden estimate, including suggestions for reducing the burden, to the Office of Management and Budget, Attention: Desk Officer for the Office of the Secretary of Transportation, 725 17th Street NW, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Deveeda Midgette, 202–366–2354, Office of Sealift Support, Maritime Administration, Department of Transportation, 1200 New Jersey Avenue SE, W26–494, Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

Title: Merchant Marine Medals and Awards.

OMB Control Number: 2133–0506.

Type of Request: Renewal of a Previously Approved Information Collection.

Background: This information collection of information provides a method of awarding merchant marine medals and decorations to masters, officers, and crew members of U.S. ships in recognition of their service in areas of danger during the operations by the Armed Forces of the United States in World War II, Korea, Vietnam, and Operation Desert Storm and Operations Restore Hope and United Shield.

Respondents: Master, officers and crew members of U.S. ships.

Affected Public: Individuals or Households.

Total Estimated Number of Responses: 550.

Frequency of Collection: Annually.

Estimated Time per Respondent: 1 hour.

Total Estimated Number of Annual Burden Hours: 550.

Public Comments Invited: Comments are invited on: 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; the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the 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; and 49 CFR 1.93)

* * * * *

Dated: March 12, 2020.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2020–05531 Filed 3–17–20; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2020–0049]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel ADONAI (Catamaran); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before April 17, 2020.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2020–0049 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2020–0049 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2020–0049, 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.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel ADONAI is:

—Intended Commercial Use of Vessel: ''Sunset Cruises & snorkel trips''
—Geographic Region Including Base of Operations: ''Florida'' (Base of Operations: Tavernier, FL)
—Vessel Length and Type: 56′ catamaran

The complete application is available for review identified in the DOT docket as MARAD–2020–0049 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov,* keyword search MARAD–2020–0049 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

* * * * *

Dated: March 12, 2020.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2020–05540 Filed 3–17–20; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF THE TREASURY

Bureau of the Fiscal Service

Proposed Collection of Information: Application for Recognition as Natural Guardian of a Minor Not Under Legal Guardianship and for Disposition of Minor's Interest in Registered Securities

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and

other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. Currently the Bureau of the Fiscal Service within the Department of the Treasury is soliciting comments concerning the Application for Recognition as Natural Guardian of a Minor Not Under Legal Guardianship and for Disposition of Minor's Interest in Registered Securities.

DATES: Written comments should be received on or before May 18, 2020 to be assured of consideration.

ADDRESSES: Direct all written comments and requests for additional information to Bureau of the Fiscal Service, Bruce A. Sharp, Room #4006–A, PO Box 1328, Parkersburg, WV 26106–1328, or *bruce.sharp@fiscal.treasury.gov.*

SUPPLEMENTARY INFORMATION:

Title: Application for Recognition as Natural Guardian of a Minor Not Under Legal Guardianship and for Disposition of Minor's Interest in Registered Securities.

OMB Number: 1530–0041.

Form Number: FS Form 2481.

Abstract: The information is collected to apply for recognition as a natural guardian and request disposition of securities belonging to a minor in situations where a natural guardian is no longer acting or a legal representative is not appointed.

Current Actions: Extension of a previously approved collection.

Type of Review: Regular.

Affected Public: Households and Individuals.

Estimated Number of Respondents: 1,250.

Estimated Time per Respondent: 10 minutes.

Estimated Total Annual Burden Hours: 208.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: 1. Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; 2. the accuracy of the agency's estimate of the burden of the collection of information; 3. ways to enhance the quality, utility, and clarity of the information to be collected; 4. ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and 5. estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: March 13, 2020.

Bruce A. Sharp,

Bureau PRA Clearance Officer.

[FR Doc. 2020–05594 Filed 3–17–20; 8:45 am]

BILLING CODE 4810–AS–P

DEPARTMENT OF THE TREASURY

Bureau of the Fiscal Service

Proposed Collection of Information: Annual Financial Statement of Surety Companies—Schedule F

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. Currently the Bureau of the Fiscal Service within the Department of the Treasury is soliciting comments concerning Annual Financial Statement of Surety Companies–Schedule F.

DATES: Written comments should be received on or before May 18, 2020 to be assured of consideration.

ADDRESSES: Direct all written comments and requests for additional information to Bureau of the Fiscal Service, Bruce A. Sharp, Room #4006–A, P.O. Box 1328, Parkersburg, WV 26106–1328, or *bruce.sharp@fiscal.treasury.gov.*

SUPPLEMENTARY INFORMATION:

Title: Annual Financial Statement of Surety Companies–Schedule F.

OMB Number: 1530–0008.

Form Number: FS Form 6314.

Abstract: The form provides information used to determine the amount of unauthorized reinsurance of Treasury approved Admitted Reinsurers. This computation is necessary to ensure the solvency of companies recognized by the Treasury to write Federal surety bonds, and their ability to carry out contractual requirements.

Current Actions: Extension of a currently approved collection.

Type of Review: Regular.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 328.

Estimated Time per Respondent: Varies from 1 hour to 40 hours.

Estimated Total Annual Burden Hours: 6,724.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: 1. Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; 2. the accuracy of the agency's estimate of the burden of the collection of information; 3. ways to enhance the quality, utility, and clarity of the information to be collected; 4. ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and 5. estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: March 13, 2020.

Bruce A. Sharp,

Bureau PRA Clearance Officer.

[FR Doc. 2020–05593 Filed 3–17–20; 8:45 am]

BILLING CODE 4810–AS–P

DEPARTMENT OF THE TREASURY

Bureau of the Fiscal Service

Proposed Collection of Information: Authorization Agreement for Preauthorized Payment (SF 5510)

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. Currently the Bureau of the Fiscal Service within the Department of the Treasury is soliciting comments concerning the Standard Form 5510, ''Authorization Agreement for Preauthorized Payment''.

DATES: Written comments should be received on or before May 18, 2020 to be assured of consideration.

ADDRESSES: Direct all written comments and requests for additional information to Bureau of the Fiscal Service, Bruce A. Sharp, Room #4006–A, PO Box 1328, Parkersburg, WV 26106–1328, or *bruce.sharp@fiscal.treasury.gov.*

SUPPLEMENTARY INFORMATION:

Title: Authorization Agreement for Preauthorized Payment.

OMB Number: 1530–0015.

Form Number: SF 5510.

Abstract: The form is used to collect information from remitters (individuals and corporations) to authorize electronic fund transfers from accounts maintained at financial institutions to collect monies for government agencies.

Current Actions: Extension of a previously approved collection.

Type of Review: Regular.

Affected Public: Business or other for-profit, individuals or households, Federal Government.

Estimated Number of Respondents: 100,000.

Estimated Time per Respondent: 15 minutes.

Estimated Total Annual Burden Hours: 25,000.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (2) the accuracy of the agency's estimate of the burden of the collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (5) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: March 13, 2020.

Bruce A. Sharp,

Bureau PRA Clearance Officer.

[FR Doc. 2020–05592 Filed 3–17–20; 8:45 am]

BILLING CODE 4810–AS–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel's Special Projects Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: Notice is hereby given for an open meeting of the Taxpayer Advocacy Panel Special Projects Project Committee scheduled for Monday, March 23, 2020 and Tuesday, March 24, 2020. This meeting was originally published in the **Federal Register** on March 9, 2020, (Volume 85, Number 46, Page 13705) as a face to face meeting. Out of an abundance of caution, certain government travel has been temporarily suspended. Due to these circumstances, we will not be able to meet the 15-calendar notice threshold. This meeting will now proceed via teleconference.

DATES: The meeting will be held Monday, March 23, 2020 and Tuesday, March 24, 2020.

FOR FURTHER INFORMATION CONTACT: Antoinette Ross at 1–888–912–1227 or 202–317–4110.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel's Special Projects Committee will be held Monday, March 23, 2020, from 1:00 p.m. to 3:00 p.m. Eastern Time and Tuesday, March 24, 2020, from 1:00 p.m. until 3:00 p.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Antoinette Ross. For more information please contact Antoinette Ross at 1–888–912–1227 or 202–317–4110, or write TAP Office, 1111 Constitution Ave. NW, Room 1509, Washington, DC 20224 or contact us at the website: *http://www.improveirs.org.* The agenda will include various IRS issues.

Dated: March 12, 2020.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2020–05658 Filed 3–17–20; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Taxpayer Communications Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: Notice is hereby given for an open meeting of the Taxpayer Advocacy Panel Taxpayer Communications Project Committee scheduled for Thursday, March 26, 2020 and Friday, March 27, 2020. This meeting was originally published in the **Federal Register** on March 9, 2020, (Volume 85, Number 46, Page 13707) as a face to face meeting. Out of an abundance of caution, certain government travel has been temporarily suspended. Due to these circumstances, we will not be able to meet the 15-calendar notice threshold. This meeting will now proceed via teleconference.

FOR FURTHER INFORMATION CONTACT: Cedric Jeans at 1–888–912–1227 or 901–707–3935.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that a meeting of the Taxpayer Advocacy Panel Taxpayer Communications Project Committee will be held Thursday, March 26, 2020, from 1:00 p.m. to 3:00 p.m. Eastern Time and Friday, March 27, 2020, from 1:00 p.m. until 3:00 p.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Cedric Jeans. For more information please contact Cedric Jeans at 1–888–912–1227 or 901–707–3935, or write TAP Office, 5333 Getwell Road, Memphis, TN 38118 or contact us at the website: *http://www.improveirs.org.* The agenda will include various IRS issues.

Dated: March 12, 2020.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2020–05659 Filed 3–17–20; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Taxpayer Assistance Center Project Committee

AGENCY: Internal Revenue Service (IRS) Treasury.

ACTION: Notice of meeting.

SUMMARY: Notice is hereby given for an open meeting of the Taxpayer Advocacy Panel Taxpayer Assistance Center Project Committee scheduled for Monday, March 23, 2020 and Tuesday, March 24, 2020. This meeting was originally published in the **Federal Register** on March 9, 2020, (Volume 85, Number 46, Page 13706) as a face to face meeting. Out of an abundance of caution, certain government travel has been temporarily suspended. Due to these circumstances, we will not be able to meet the 15-calendar notice threshold. This meeting will now proceed via teleconference.

DATES: The meeting will be held Monday, March 23, 2020 and Tuesday, March 24, 2020.

FOR FURTHER INFORMATION CONTACT: Matthew O'Sullivan at 1–888–912–1227 or (510) 907–5274.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel's Taxpayer Assistance Center Project Committee will be held Monday, March 23, 2020, from 1:00 p.m. to 3:00 p.m. Eastern Time and Tuesday, March 24, 2020, from 1:00 p.m. until 3:00 p.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Matthew O'Sullivan. For more information please contact Matthew O'Sullivan at 1–888–912–1227 or (510) 907–5274, or write TAP Office, 1301 Clay Street, Oakland, CA 94612–5217 or contact us at the website: *http://www.improveirs.org*. The agenda will include various IRS issues.

Dated: March 12, 2020.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2020–05657 Filed 3–17–20; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel's Tax Forms and Publications Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: Notice is hereby given for an open meeting of the Taxpayer Advocacy Panel Tax Forms and Publications Project Committee scheduled for Monday, March 23, 2020 and Tuesday, March 24, 2020. This meeting was originally published in the **Federal Register** on March 9, 2020, (Volume 85, Number 46, Page 13706) as a face to face meeting. Out of an abundance of caution, certain government travel has been temporarily suspended. Due to these circumstances, we will not be able to meet the 15-calendar notice threshold. This meeting will now proceed via teleconference.

DATES: The meeting will be held Monday, March 23, 2020 and Tuesday, March 24, 2020.

FOR FURTHER INFORMATION CONTACT: Fred Smith at 1–888–912–1227 or (202) 317–3087.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that a meeting of the Taxpayer Advocacy Panel's Tax Forms and Publications Project Committee will be held Monday, March 23, 2020, from 1:00 p.m. to 3:00 p.m. Eastern Time and Tuesday, March 24, 2020, from 1:00 p.m. until 3:00 p.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Fred Smith. For more information please contact Fred Smith at 1–888–912–1227 or (202) 317–3087, or write TAP Office, 1111 Constitution Ave. NW, Room 1509, Washington, DC 20224 or contact us at the website: *http://www.improveirs.org.*

Dated: March 12, 2020.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2020–05655 Filed 3–17–20; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel's Toll-Free Phone Line Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: Notice is hereby given for an open meeting of the Taxpayer Advocacy Panel Toll-Free Phone Line Project Committee scheduled for Thursday, March 26, 2020 and Friday, March 27, 2020. This meeting was originally published in the **Federal Register** on March 9, 2020, (Volume 85, Number 46, Page 13706) as a face to face meeting. Out of an abundance of caution, certain government travel has been temporarily suspended. Due to these circumstances, we will not be able to meet the 15-calendar notice threshold. This meeting will now proceed via teleconference.

FOR FURTHER INFORMATION CONTACT: Rosalind Matherne at 1–888–912–1227 or 202–317–4115.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel Toll-Free Phone Line Project Committee will be held Thursday, March 26, 2020, from 1:00 p.m. to 3:00 p.m. Eastern Time and Friday, March 27, 2020, from 1:00 a.m. until 3:00 p.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Rosalind Matherne. For more information please contact Rosalind Matherne at 1–888–912–1227 or 202–317–4115, or write TAP Office, 1111 Constitution Ave. NW, Room 1509, Washington, DC 20224 or contact us at the website: *http://www.improveirs.org*. The agenda will include various IRS issues.

Dated: March 12, 2020.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2020–05660 Filed 3–17–20; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel's Notices and Correspondence Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: Notice is hereby given for an open meeting of the Taxpayer Advocacy Panel Tax Notices and Correspondence Project Committee scheduled for Thursday, March 26, 2020 and Friday, March 27, 2020. This meeting was originally published in the **Federal Register** on March 9, 2020 (Volume 85, Number 46, Page 13708), as a face to face meeting. Out of an abundance of caution, certain government travel has been temporarily suspended. Due to these circumstances, we will not be able to meet the 15-calendar notice threshold. This meeting will now proceed via teleconference.

DATES: The meeting will be held Thursday, March 26, 2020 and Friday, March 27, 2020.

FOR FURTHER INFORMATION CONTACT: Robert Rosalia at 1–888–912–1227 or (718) 834–2203.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel's Notices and Correspondence Project Committee will

be held Thursday, March 26, 2020, from 1:00 p.m. to 3:00 p.m. Eastern Time and Friday, March 27, 2020, from 1:00 p.m. until 3:00 p.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Robert Rosalia. For more information please contact Robert Rosalia at 1–888–912–1227 or (718) 834–2203, or write TAP Office, 2 Metrotech Center, 100 Myrtle Avenue, Brooklyn, NY 11201 or contact us at the website: *http://www.improveirs.org.* The agenda will include various IRS issues.

Dated: March 12, 2020.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2020–05656 Filed 3–17–20; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

United States Mint

2020 Pricing of Numismatic Gold, Commemorative Gold, Platinum, and Palladium Products Grid

AGENCY: United States Mint, Department of the Treasury.

ACTION: Notice.

SUMMARY: The United States Mint announces 2020 revisions to include price increases for the American Eagle Gold Proof Coin, American Eagle Gold Uncirculated Coin, American Buffalo Gold Proof Coin, American Eagle Palladium Coin, American Liberty Gold Coin, and commemorative proof and uncirculated gold coin products within the Pricing of Numismatic Gold, Commemorative Gold, Platinum, and Palladium Products Grid.

FOR FURTHER INFORMATION CONTACT: Cathy Olson; Sales and Marketing Directorate; United States Mint; 801 9th Street NW, Washington, DC 20220; or call 202–354–7500.

SUPPLEMENTARY INFORMATION: An excerpt of the grid with a recent price range for the American Eagle Gold Proof coins appears below:

2020 Pricing of Numismatic Gold, Commemorative Gold, Platinum, and Palladium Products

*Does not reflect $5 discount during introductory period

Average Price per Ounce	Size	American Eagle Gold Proof	American Eagle Gold Uncirculated	American Buffalo 24K Gold Proof	American Eagle Platinum Proof	American Eagle Palladium Reverse Proof	American Liberty 24K Gold	Commemorative Gold Proof*	Commemorative Gold Uncirculated*
$1600.00 to $1649.99	1 oz	$2,275.00	$2,240.00	$2,315.00	$2,195.00	$2,300.00	$2,340.00		
	1/2 oz	$1,155.00							
	1/4 oz	$ 590.00							
	1/10 oz	$ 250.00					$ 280.00		
	4-coin set	$4,225.00							
	commemorative gold							$ 625.00	$ 615.00
	commemorative 3-coin set							$ 690.50	

The complete 2020 Pricing of Numismatic Gold, Commemorative Gold, Platinum, and Palladium Products Grid will be available at *https://catalog.usmint.gov/coin-programs/american-eagle-coins.*

Pricing can vary weekly dependent upon the London Bullion Market Association gold, platinum, and palladium prices weekly average. The pricing for all United States Mint numismatic gold, platinum, and palladium products is evaluated every Wednesday and modified as necessary.

Authority: 31 U.S.C. 5111, 5112, & 9701.

Dated: March 12, 2020.

David J. Ryder,

Director, United States Mint.

[FR Doc. 2020–05604 Filed 3–17–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF VETERANS AFFAIRS

Geriatric and Gerontology Advisory Committee, AMENDED, Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act that a meeting of the Geriatric and Gerontology Advisory Committee will be held on Wednesday, April 1, 2020 from 12 p.m. to 5 p.m. (Eastern Daylight Time). This meeting will be virtual and open to the public.

The purpose of the Committee is to provide advice to the Secretary of VA and the Under Secretary for Health on all matters pertaining to geriatrics and gerontology. The Committee assesses the capability of VA health care facilities and programs to meet the medical, psychological, and social needs of older Veterans, and evaluates VA programs designated as Geriatric Research, Education, and Clinical Centers.

Although no time will be allocated for receiving oral presentations from the public, members of the public may submit written statements for review by the Committee to: Ms. Marianne Shaughnessy, CRNP, Ph.D., Designated Federal Officer, Veterans Health Administration (10NC4), 810 Vermont Avenue NW, Washington, DC 20420 or by email at *Marianne.Shaughnessy@va.gov.* Comments will be accepted until close of business on March 27, 2020. In the communication, the writers must identify themselves and state the organization, association of person(s) they represent.

Any member of the public wishing to attend virtually or seeking additional information should email *Marianne.Shaughnessy@va.gov* or call 202–461–7217, no later than close of business on March 27, 2020 to provide their name, professional affiliation, email address and phone number. The call-in number is 1–800–767–1750; Access Code: 17499#.

Dated: March 13, 2020.

LaTonya L. Small,

Federal Advisory Committee Management Officer.

[FR Doc. 2020–05605 Filed 3–17–20; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Veterans' Family, Caregiver, and Survivor Advisory Committee, Notice of Meeting, Amended

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act (FACA) that the Veterans' Family, Caregiver, and

Survivor Advisory Committee will meet virtually on March 25, 2020. The meeting sessions will begin and end as follows:

Date	Time
March 25, 2020 ..	9:00 a.m. to 11:30 a.m. EST.

The meetings are open to the public. Members of the public can attend the meeting via teleconference (800) 767–1750 access code 64895#.

The purpose of the Committee is to advise the Secretary of Veterans Affairs on matters related to: The need of Veterans' families, caregivers, and survivors across all generations, relationships, and Veterans status; the use of VA care, benefits and memorial services by Veterans' families, caregivers, and survivors, and opportunities for improvements to the experience using such services; VA policies, regulations, and administrative requirements related to the transition of Servicemembers from the Department of Defense (DoD) to enrollment in VA that impact Veterans' families, caregivers, and survivors; and factors that influence access to, quality of, and accountability for services, benefits and memorial services for Veterans' families, caregivers, and survivors.

On March 25, the agenda will include opening remarks from the Committee Chair and the Chief Veterans Experience Officer. There will be updates on Program of Comprehensive Assistance for Family Caregivers, and caregiver research conducted by the Elizabeth Dole Foundation.

Individuals wishing to share information with the Committee should contact Ms. Toni Bush Neal (Alternate Designated Federal Official) at *VEOFACA@va.gov* to submit a 1–2 page summary of their comments for inclusion in the official meeting record.

Any member of the public seeking additional information should contact Betty Moseley Brown (Designated Federal Official) at *Betty.MoseleyBrown@va.gov* or (210) 392–2505.

Dated: March 12, 2020.

Jelessa M. Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2020–05574 Filed 3–17–20; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Veterans Rural Health Advisory Committee; Notice of Meeting—Cancellation

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act that the meeting of the Veterans Rural Health Advisory Committee previously scheduled to be held on April 15–16, 2020, at Raymond G. Murphy VA Medical Center, 1501 San Pedro Dr. SE, Albuquerque, NM 87108 has *been cancelled*. For more information, please contact Mr. Thomas Klobucar, Designated Federal Officer at (202) 632–8581, or via email at *Thomas.Klobucar@va.gov*.

Dated: March 13, 2020.

LaTonya L. Small,

Federal Advisory Committee Management Officer.

[FR Doc. 2020–05663 Filed 3–17–20; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 85 Wednesday,

No. 53 March 18, 2020

Part II

Federal Reserve System

12 CFR Parts 217, 225, and 252

Regulations Q, Y, and YY: Regulatory Capital, Capital Plan, and Stress Test Rules; Final Rule

FEDERAL RESERVE SYSTEM

12 CFR Parts 217, 225, and 252

[Docket No. R–1603]

RIN 7100–AF02

Regulations Q, Y, and YY: Regulatory Capital, Capital Plan, and Stress Test Rules

AGENCY: Board of Governors of the Federal Reserve System (Board).

ACTION: Final rule.

SUMMARY: The Board is adopting a rule (final rule) that simplifies the Board's capital framework while preserving strong capital requirements for large firms. The final rule would integrate the Board's regulatory capital rule (capital rule) with the Comprehensive Capital Analysis and Review (CCAR), as implemented through the Board's capital plan rule (capital plan rule). The final rule makes amendments to the capital rule, capital plan rule, stress test rules, and Stress Testing Policy Statement. Under the final rule, the Board will use the results of its supervisory stress test to establish the size of a firm's stress capital buffer requirement, which replaces the static 2.5 percent of risk-weighted assets component of a firm's capital conservation buffer requirement. Through the integration of the capital rule and CCAR, the final rule would remove redundant elements of the current capital and stress testing frameworks that currently operate in parallel rather than together, including the CCAR quantitative objection and the assumption that a firm makes all capital actions under stress. The final rule applies to bank holding companies and U.S. intermediate holding companies of foreign banking organizations that have $100 billion or more in total consolidated assets.

DATES: Effective May 18, 2020.

FOR FURTHER INFORMATION CONTACT: Lisa Ryu, Senior Associate Director, (202) 263–4833, Constance Horsley, Deputy Associate Director, (202) 452–5239, Juan Climent, Manager (202) 872–7526, Andrew Willis, Lead Financial Institution Policy Analyst, (202) 912–4323, Christopher Appel, Senior Financial Institution Policy Analyst II, (202) 973–6862, Hillel Kipnis, Senior Financial Institution Policy Analyst II, (202) 452–2924, and Palmer Osteen, Financial Institution Policy Analyst, (202) 785–6025, Division of Supervision and Regulation; Benjamin McDonough, Assistant General Counsel, (202) 452–2036, Julie Anthony, Senior Counsel, (202) 475–6682, Mark Buresh, Senior Counsel, (202) 452–5270, Asad Kudiya, Senior Counsel, (202) 475–6358, or Mary Watkins, Senior Attorney, (202) 452–3722, Legal Division, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551. Users of Telecommunication Device for Deaf (TDD) only, call (202) 263–4869.

SUPPLEMENTARY INFORMATION:

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I. Introduction

Over the past ten years, stress testing has become a fundamental element of the Federal Reserve's supervision program for large banking organizations. In the same time period, the Board has strengthened the ongoing regulatory capital requirements applicable to these firms. On April 10, 2018, the Board issued a proposal to simplify its stress testing and regulatory capital frameworks with the introduction of the stress capital buffer requirement (the proposal).[1] This final rule adopts the stress capital buffer requirement set forth in the proposal with certain adjustments. As in the proposal, the Board will use the results of its supervisory stress test to determine a firm's stress capital buffer requirement. A firm's stress capital buffer requirement, which varies based on a firm's risk, replaces the fixed 2.5 percent of risk-weighted assets portion of its capital conservation buffer requirement. A firm that does not maintain capital ratios above its minimums plus its buffer requirements faces restrictions on its capital distributions and discretionary bonus payments. This approach integrates CCAR with the capital rule, simplifies the Board's overall approach to capital regulation, and preserves strong capital requirements. Separate from the final rule, the Board intends to propose at a future date modifications to further simplify and increase the transparency of the stress testing framework.

II. Background and Overview of the Final Rule

A. Background on the Stress Testing and Regulatory Capital Frameworks

At the height of the 2008–2009 financial crisis, the Board created the Supervisory Capital Assessment Program (SCAP) as a way to help restore confidence in the largest U.S. banking organizations. SCAP estimated potential losses at those firms assuming that economic and financial conditions worsened. Building on the success of SCAP, the Board implemented the capital plan rule, which requires the largest firms to develop and maintain capital plans supported by robust processes for assessing their capital adequacy. The CCAR exercise established a quantitative assessment of firms' capital adequacy for all subject firms and a qualitative assessment of the capital planning practices of the largest and most complex firms' capital planning practices. The quantitative assessment includes an evaluation of firms' capital adequacy and their ability to continue to lend and absorb potential losses under severely adverse conditions. Under the CCAR quantitative evaluation, a firm is required to demonstrate the ability to maintain capital ratios above the minimum requirements under stress, taking into account nine quarters of planned capital distributions. In the qualitative assessment, the Federal Reserve evaluated how the largest and most complex firms identify, measure,

[1] *See* 80 FR 18160 (April 25, 2018).

and determine capital needs for their material risks.

At the same time that the Board was building the stress testing program, it was also making changes to its capital rule to address weaknesses observed during the 2008–2009 financial crisis.[2] These changes included the establishment of a minimum common equity tier 1 (CET1) capital requirement and a fixed capital conservation buffer equal to 2.5 percent of risk-weighted assets.[3] Large banking organizations also became subject to a countercyclical capital buffer requirement, and the largest and most systemically important firms—global systemically important bank holding companies, or GSIBs—became subject to an additional capital buffer based on a measure of their systemic risk, the GSIB surcharge.[4] The capital rule's buffer requirements impose increasingly strict automatic limits on capital distributions as a firm's capital ratios decline toward the minimum requirements. For example, a firm in the bottom quartile of its capital conservation buffer may not make any capital distributions without prior approval from the Board.

Stress testing and stronger capital requirements have significantly improved the resilience of the U.S. banking system. The common equity capital ratios of firms subject to CCAR have more than doubled since 2009. Combined, these firms hold more than $1 trillion of CET1 capital. Notwithstanding these important improvements, the Board believes it is prudent to periodically review its regulations to ensure they are achieving their goals in an effective and efficient manner. Importantly, although the capital plan rule and the capital rule share similar goals, they were developed separately, and this has led to certain significant redundancies in the Board's capital framework. In keeping with other recent efforts to improve the efficiency and risk-sensitivity of its regulations, the Board is adopting this final rule to integrate the overlapping requirements in the capital plan rule and the capital rule to increase the efficiency and simplicity of the Board's capital framework while maintaining its risk sensitivity and improvements in capital adequacy.

B. Overview of the Proposed Rule and Summary of Comments

Under the proposed rule, for each firm subject to the capital plan rule, the Board would have calculated a stress capital buffer requirement based on the results of the supervisory stress test and four quarters of planned common stock dividends. The stress capital buffer requirement would have replaced the fixed 2.5 percent component of a firm's capital conservation buffer requirement. The proposal also would have introduced a stress leverage buffer on top of the 4 percent minimum leverage ratio requirement for firms subject to the capital plan rule. A firm's stress capital buffer requirement would have been ''floored'' at 2.5 percent of risk-weighted assets, whereas the stress leverage buffer requirement would not have included a floor. A firm would have been required to maintain risk-based and leverage-based capital ratios above its buffer requirements in order to avoid restrictions on its capital distributions and certain discretionary bonus payments. The proposal also would have made changes to the Board's capital plan and stress test rules and related policy statements, and would have eliminated: (1) The assumption that a firm would make all planned capital distributions over the planning horizon, (2) the assumption that a firm's balance sheet assets would increase over the planning horizon, (3) the quantitative objection in CCAR; and (4) the 30 percent dividend payout ratio as a criterion for heightened scrutiny of a firm's capital plan.

The Board received twenty-six comments on the proposal from banking organizations, public interest groups, private individuals, and other interested parties. Many commenters were supportive of the proposal's goal of integrating CCAR and the Board's capital rule. Commenters had mixed views, however, on the calibration of the stress capital buffer requirement, the need for a stress leverage buffer, the proposed changes to the assumptions in the Board's stress testing framework, and the flexibility provided to firms in their capital planning.[5]

Some commenters asserted that the proposed stress capital buffer requirement was too stringent, particularly when combined with the GSIB surcharge and the countercyclical capital buffer, and suggested alternatives. Other commenters asserted that it was important for the Federal Reserve to not take action that would lower capital requirements for any firm given improvements in capital since the 2008–2009 financial crisis and that the Board should retain the assumption that firms make nine quarters of dividends and share repurchases in the stress test.

Some commenters urged the Board to eliminate the proposed stress leverage buffer requirement, noting that its inclusion adds complexity to capital requirements and is inconsistent with the role of the leverage ratio as a backstop to risk-based capital requirements. These commenters were concerned that the proposed stress leverage buffer requirement would increase the probability that a banking organization's binding post-stress capital constraint would be a leverage requirement rather than a risk-based requirement. Some of these commenters argued that there should be a clearer delineation between the capital framework's risk-based and non-risk-based measures. Other commenters supported adopting the proposed stress leverage buffer requirement and urged the Board to retain a post-stress capital requirement for the supplementary leverage ratio to maintain the practice of evaluating off-balance sheet exposures in the supervisory stress test.

Regarding the proposed changes to the assumptions in the stress test, some commenters argued that the Board should not include four quarters of common stock dividends in the stress capital buffer requirement because the capital rule already contains a distribution limitation mechanism to restrict a firm from making dividend payments if its capital ratios were at or below its minimums plus buffer requirements. Other commenters argued that not only should the Board include four quarters of dividends in the stress capital buffer requirement, but that the Board also should retain its assumption that a firm makes nine quarters of share repurchases and dividends as certain firms made dividend payments and executed share repurchases well into the beginning of the 2008–2009 financial crisis.

Several commenters supported the proposed modifications to the balance sheet growth assumptions. Other commenters asserted that the Board should assume that trading assets would decline under stress, as such a reduction would align with reasonable expectations under stress. Still other commenters disagreed with the proposed modification to the balance sheet growth assumptions, as the current assumption that balance sheet assets would grow over the planning horizon helped to ensure that firms can lend and support the real economy during stress. These commenters were concerned that the proposed revisions would not ensure that banks would

[2] *See* 12 CFR part 217.

[3] *See* 12 CFR 217.11.

[4] *See* 80 FR 49082 (August 14, 2015).

[5] The Board received a number of comments that were outside of the scope of the proposal. In particular, commenters recommended further revisions related to the U.S. GSIB capital surcharge rule, total loss absorbing capacity rule, and current expected credit losses standard.

continue their credit intermediation function during a recession.

Some commenters asserted that, in light of the proposal integrating CCAR with the capital rule, the Board should address the potential volatility of Board's stress testing framework, including revising the Board's scenario design process and revising the definition of eligible retained income in the capital rule to ensure that the distribution restrictions in the capital rule gradually restrict a firm's ability to make capital distributions. Finally, regarding the ability of a firm to make distributions in excess of those in its capital plan, some commenters supported allowing the firm to exceed its planned capital distributions if its capital ratios were above those projected in the bank holding company baseline scenario projections.[6] Others recommended allowing a firm to increase its planned capital distributions without prior approval from the Board as long as the firm did not exceed the distributions permitted under the capital rule's capital conservation buffer requirement. Other commenters supported maintaining the requirement that a firm seek approval from the Board before making capital distributions in excess of those in its capital plan, arguing that removing this requirement would weaken capital standards by allowing banks additional leeway in making capital distributions.

C. Overview of the Final Rule

The final rule integrates the capital plan rule and the capital rule by using the results of the supervisory stress test to establish a firm's stress capital buffer requirement and establish a unified approach to capital distribution limitations. Specifically, a firm's stress capital buffer requirement is calculated as: (1) The difference between the firm's starting and minimum projected CET1 capital ratios under the severely adverse scenario in the supervisory stress test (stress test losses) plus (2) the sum of the dollar amount of the firm's planned common stock dividends for each of the fourth through seventh quarters of the planning horizon as a percentage of risk-weighted assets (dividend add-on).[7] A firm must maintain capital ratios above the sum of its minimum requirements and buffer requirements in order to avoid restrictions on capital distributions and discretionary bonus payments.

In a change from the proposal, the final rule does not include a stress leverage buffer requirement in order to maintain a clear distinction between the capital framework's risk-based and non-risk-based capital requirements. In addition, to address the potential volatility of the stress capital buffer requirement and to ensure that the distribution limitations in the capital rule work as intended, the final rule revises the definition of eligible retained income to a quarterly average net income measure under certain conditions.

The final rule adjusts the distribution assumptions used in CCAR by no longer presuming that a firm will make all planned capital distributions, including common stock dividends and repurchases, over the nine-quarter planning horizon. Instead, a firm's stress capital buffer requirement includes four quarters of planned common stock dividends (in the fourth through seventh quarters of the nine-quarter planning horizon). In a change from the proposal, to simplify the calculation of the dividend add-on and to create consistency between the calculation of the dividend add-on and the portion of the stress capital buffer requirement attributable to the decline in CET1 ratios, the Board will no longer calculate the dividend add-on as the sum of the ratios of the dollar amount of the firm's planned common stock dividends divided by the projected risk-weighted assets for each of the fourth through seventh quarters of the planning horizon. Instead the divided-add-on will be calculated by dividing the sum of the four quarters of planned common stock dividends by the projected risk-weighted assets from the quarter in which the firm's projected CET1 capital ratio reaches its minimum in the supervisory stress test.

In addition, the final rule adjusts the methodology used in the supervisory stress test to assume that a firm takes actions to maintain a constant level of assets, including loans, trading assets, and securities over the planning horizon. In a change from the proposal, to simplify the stress test and to avoid potentially double-counting the impact of a merger or acquisition, the stress capital buffer requirement in the final rule does not include the projected impact of material business plan changes. Instead, any impact of these business changes will be reflected in a firm's ongoing capital ratios once the business plan change is consummated. As in current CCAR, the Board may require a firm to resubmit its capital plan and recalculate the firm's stress capital buffer requirement in the event of material business changes.

The final rule also modifies certain elements in CCAR to further the goal of establishing a unified approach to capital distribution limitations. Specifically, the final rule eliminates the once-a-year quantitative objection process, given the integration of stress-test results into the stress capital buffer requirement's automatic distribution limitations.[8] Relatedly, the final rule eliminates the 30 percent dividend payout ratio as a criterion for heightened scrutiny of a firm's capital plan.

Finally, while the final rule continues to require a firm to describe its planned capital distributions in a capital plan, a firm is no longer required to seek prior approval if it makes capital distributions in excess of those included in its capital plan (so long as the firm is otherwise in compliance with the capital rule's automatic restrictions on distributions). This approach harmonizes the approach to capital distributions in the capital plan rule and the capital rule. A similar change was made to provide additional flexibility in the ''adjustment process'' to permit a firm to increase its planned capital distributions upon receipt of its initial stress capital buffer requirement.[9]

III. The Stress Capital Buffer Requirement

This section describes the calculation of the stress capital buffer requirement, including its calibration, and the changes to the assumptions in the Board's stress testing framework. The final rule adopts the calculation of the stress capital buffer requirement as proposed. It also includes a revised definition of eligible retained income, which affects how the stress capital buffer requirement limits capital distributions. As discussed below, and in response to comments, the final rule does not include a stress leverage buffer requirement.

[6] The capital plan rule requires firms to submit a request to the Board for approval of a capital distribution that exceeds the amount of capital distributions described in a firm's annual capital plan submission.

[7] The planning horizon is the period of at least nine consecutive quarters over which the relevant projections extend, beginning with the quarter preceding the quarter in which the firm submits its capital plan.

[8] In March 2019, the Board eliminated the CCAR qualitative objection for most firms. 84 FR 8953 (March 13, 2019). Specifically, a firm that participates in four assessments and successfully passes the qualitative evaluation in the fourth year is no longer subject to a potential qualitative objection.

[9] Upon completion of the supervisory stress test, the Federal Reserve will provide each firm with the results of its post-stress capital analysis, and each firm will have an opportunity to make a one-time adjustment to its planned capital actions.

A. Assumptions, Methodologies and Calculation Mechanics Used in Determining the Stress Capital Buffer Requirement

The calculation of the stress capital buffer requirement generally includes the changes described in the proposal related to capital distribution and balance sheet assumptions. This section discusses the comments received on the proposed calculation of the stress capital buffer requirement and changes made in response to comments.

i. Capital Distribution Assumptions

In its assessment of capital plans through CCAR, the Board assumed that a firm would make all nine quarters of its planned capital distributions, including dividend payments and share repurchases, under stress. The proposal would have modified this assumption to no longer assume that a firm made these planned capital distributions but, instead, would have included four quarters of planned common stock dividends in the calculation of the stress capital buffer requirement. In addition, the proposal would have eliminated the 30 percent dividend payout ratio as a criterion for heightened scrutiny of a firm's capital plan.

Commenters generally were supportive of the proposal to eliminate all nine quarters of planned capital distributions. Several commenters similarly were opposed to including four quarters of planned dividends in the calculation of the stress capital buffer requirement, viewing it as unnecessary, complicated, and unduly punitive given the capital rule's existing automatic restrictions on capital distributions. These commenters asserted that if the Board maintains this requirement, it should allow a firm to continue to pay its planned dividends if the firm's capital ratios were in the dividend add-on portion of its buffer requirements. In addition, several commenters asserted that the underlying rationale for including four quarters of planned dividends does not apply to U.S. intermediate holding companies of foreign banking organizations given their ownership structures.

Other commenters were supportive of including distributions in the calculation of the stress capital buffer requirement to create strong incentives for disciplined, forward-looking capital planning. Some commenters also argued that requiring a four-quarter dividend add-on is arbitrary and inconsistent with historical experience, while other commenters recommended that repurchases and redemptions should also factor into the stress capital buffer requirement.

After considering these comments, the Board is adopting the proposed changes to the capital distribution assumptions, as proposed. Although including four quarters of planned common stock dividends in the calculation of a firm's stress capital buffer requirement adds a level of complexity to the stress capital buffer requirement calculation process, this approach is one way of promoting forward-looking dividend planning given historical experience. During the last financial crisis, many firms continued to make significant distributions of capital, including through dividends, without due consideration of the effects that a prolonged economic downturn could have on their capital adequacy. In addition, the dividend add-on requirement is one way to mitigate the procyclicality of the Board's stress testing framework, because dividends tend to be higher when the economy is strong and earnings are high.[10]

To further simplify the Board's stress test framework, the final rule also removes the 30 percent dividend payout ratio applied as a criterion for heightened supervisory scrutiny of a firm's capital plan. This criterion was adopted to encourage firms to increase payouts through additional share repurchases rather than dividends. A dividend payout ratio criterion is no longer necessary because the final rule's automatic distribution limitations, combined with the perceived market signaling effect of dividend cuts, will sufficiently restrict dividend increases in the future.

One commenter suggested that the Board include issuances related to employee compensation in the stress capital buffer requirement calculation as an offset to the impact on retained earnings that would be embedded in the stress test results. The final rule does not include most other capital actions in the stress test and excluding employee stock issuances, along with related share repurchases, is consistent with this approach. This approach also will make the stress test results more comparable across firms and more transparent to the public. Similar to other capital actions that are not included in the stress test results, in real-time, issuances related to employee compensation increase a firm's capital ratio and, therefore, impact the firm's ability to avoid the automatic distribution limitations. For these reasons, the final rule excludes such issuances in the calculation of the stress capital buffer requirement, consistent with the proposal.

ii. Balance Sheet Assumption

Under the proposal, the Board would have modified its methodology for projecting a firm's balance sheet in the supervisory stress test. The proposal would have updated the Board's Stress Testing Policy Statement to include the assumption that a firm takes actions to maintain its current level of assets, including securities, trading assets, and loans, over the planning horizon.[11] This assumption would have simplified the current supervisory stress test and also dissuaded firms from planning to reduce credit supply in a stress scenario. In addition, the proposal would have revised the Stress Testing Policy Statement to reflect that, in its projections, the Board would assume that a firm's risk-weighted assets and leverage ratio denominator remain unchanged over the planning horizon except for changes primarily related to deductions from regulatory capital or changes in the Board's regulations.

Many commenters supported the proposed change to assume that the size of a firm's balance sheet remains constant over the planning horizon, arguing that this change would make the supervisory projections more realistic. Commenters opposing the proposed change argued that the Federal Reserve should continue to model balance sheet growth, noting that bank balance-sheets have grown during periods of stress and that CCAR should continue to evaluate whether a firm could continue to provide credit and support the real economy. Other commenters suggested that rather than assuming no growth, the Board's projections should assume that market declines and losses would reduce trading assets and risk-weighted assets. Commenters also requested that the Board require firms to make consistent assumptions in stress tests conducted by the firm.

Consistent with the proposal, the final rule revises the Board's Stress Testing Policy Statement to include the assumption that a firm takes actions to

[10] As in the current supervisory post-stress capital assessment, the Board will continue to assume in the supervisory stress test that a firm will make payments on any instrument that qualifies as additional tier 1 capital or tier 2 capital equal to the stated dividend, or contractual interest or principal due on such instrument during the quarter. Based on supervisory experience, reductions in these payments are generally viewed by market participants as a sign of material weakness, and firms are therefore likely to make them even under stressful conditions (*see* 12 CFR 217.20(c) and (d)).

[11] While the Board will assume in the supervisory post-stress capital assessment that a firm's balance sheet does not grow, in a firm's company-run stress tests, the Board expects each firm's projected balance sheet to be consistent with each scenario and the firm's business strategy.

maintain its current level of assets over the planning horizon. Although a firm's balance sheet may change in different ways in periods of stress, a constant balance sheet assumption simplifies the Board's stress testing framework, while dissuading firms from planning to reduce credit supply in a stress scenario.

iii. Business Plan Changes

Similar to the Board's current methodology, the proposal would have reflected the impact of expected changes to a firm's business plan that are likely to have a material impact on the firm's capital adequacy and funding profile (material business plan changes) in balance sheet, risk-weighted asset, and leverage ratio denominator projections for purposes of calculating the stress capital buffer requirement.[12] One commenter suggested that the Board not reflect the impact of a material business plan change, such as a merger or acquisition, in a firm's stress capital buffer requirement because the impact would be reflected in the firm's balance sheet and risk-weighted assets once the merger or acquisition is consummated. This commenter argued that this approach would result in double-counting the impact of a merger or acquisition.

The final rule does not incorporate material business plan changes in a firm's stress capital buffer requirement. For example, planned issuances of common or preferred stock in connection with a planned merger or acquisition will not be included in the stress capital buffer requirement calculation. In addition, any planned common stock dividends attributable to issuances that would be made in connection with a planned merger or acquisition will also not be included in the stress capital buffer requirement calculation.[13] Excluding material business plan changes from the stress capital buffer requirement would simplify the framework and reduce burden. Material changes to a firm's business plan resulting from a merger or acquisition are incorporated into a firm's capital and risk-weighted assets upon consummation of the transaction. Including these changes in a firm's stress capital buffer requirement may overstate the impact of the business plan change while also adding complexity associated with predicting the impact of the material change in a firm's balance sheet.

In addition, the final rule would continue to require a firm to include in its capital plan a discussion of any expected changes to the firm's business plan that are likely to have a material impact on the capital adequacy or liquidity position of the firm. This requirement would help to ensure that a firm appropriately plans for changes to its business. If the material business plan change resulted in or would result in a material change in a firm's risk profile, the firm would be required to resubmit its capital plan and the Board may determine to recalculate the stress capital buffer requirement based on the resubmitted capital plan.

The final rule would make conforming changes to the Board's stress testing rules to align with exclusion of material business plan changes in the calculation of the stress capital buffer requirement. The final rule also would make conforming changes to the Stress Test Policy Statement.

iii. Calculation Mechanics

The proposal would have established a firm's stress capital buffer requirement based on the difference between the firm's starting and minimum projected CET1 capital ratios under the severely adverse scenario in the supervisory stress test. One commenter argued that the stress capital buffer requirement should be based on absolute dollar values of capital depletion rather than ratios, because a firm's losses in the stress test do not necessarily correspond to risk-weighted assets or total balance-sheet assets. In addition, one commenter argued for more frequent recalibration of a firm's stress capital buffer requirement.[14]

To ensure the capital framework is sufficiently risk-sensitive, the stress capital buffer requirement under the final rule is based on projected changes in a firm's capital ratio.[15] Using the change in projected capital ratios, and not the projected dollars of losses, allows a firm's capital requirements to be sensitive to changes in its risk-weighted assets throughout the year. Under this approach, the Federal Reserve assumes that stress losses are related to a firm's risk-weighted assets. Under the commenter's recommendation, any increase in risk-weighted assets during the course of the year would be treated as having zero dollars of losses in the stress test, thereby reducing risk sensitivity of the capital requirements. With respect to frequency of the stress capital buffer requirement calculation, calculating the stress capital buffer requirement with the same frequency as the stress test promotes both stability in capital requirements and risk sensitivity. As discussed in Section IV.F, if a firm experiences or will experience a material change in its risk profile, the Board may determine to recalculate the firm's stress capital buffer requirement. The Board is therefore adopting the calculation of the stress capital buffer requirement as proposed.

B. Volatility of Capital Requirements and Severity of Scenarios

i. Predictability of Capital Requirements and Stress Test Scenario Volatility

Commenters raised concerns about potential volatility in capital requirements as a result of the Board's stress testing framework under the proposal. Some commenters suggested calculation changes to limit the year-over-year changes in a firm's stress capital buffer requirement. Another commenter suggested reducing volatility by basing the stress capital buffer requirement on firm-developed models, to be reviewed by the Federal Reserve.

While the proposal would not have amended the Board's scenario design framework, commenters recommended that the Board enhance the transparency of the scenario design process, including by providing more parameters and shock ranges, in order to reduce the uncertainty associated with capital requirements. Commenters had a number of recommendations for enhancing the transparency of scenarios used in the supervisory stress test. Many commenters supported publishing each year's severely adverse scenario for notice and comment. Other commenters, however, thought that publishing the scenario for comment may lead to pressure to not include salient risks that reflect current market conditions.

Some degree of volatility is inherent to risk-based capital requirements, including those determined by stress testing, as such requirements are sensitive to changes in a firm's activities, exposures and changes to macroeconomic conditions. In addition, some volatility in stress test results is to be expected because the stress test is

[12] A firm's capital plan must include a discussion of any expected changes to its business plan that are likely to have a material impact on the firm's capital adequacy or liquidity. *See* 12 CFR 225.8(e)(2)(iv).

[13] Specifically, the dividend add-on portion of a firm's stress capital buffer requirement will exclude dividends planned for the fourth through seventh quarters of the planning horizon to the extent that these dividends are associated with a material business plan change. To isolate and exclude dividends associated with a material business plan change from other dividends, the Board will rely on information submitted in the capital plans and may collect additional information from firms.

[14] *See* Section IV.F for further discussion on the recalculation of the stress capital buffer requirement.

[15] A firm's stress capital buffer requirement will be calculated up to a single decimal place (*e.g.*–2.7).

designed to capture a firm's vulnerability to plausible and salient risks to the U.S. financial system. The Federal Reserve continues to study potential ways to mitigate unnecessary volatility in requirements, while retaining plausible changes in the scenarios to reflect changing risks.

To provide firms and the public with greater transparency regarding the Board's process for designing supervisory scenarios for stress testing, in 2013 the Board finalized a Policy Statement on the Scenario Design Framework for Stress Testing (Scenario Policy Statement).[16] On February 5, 2019, the Board released materials intended to increase the transparency of the stress testing program.[17] First, the Board updated the Scenario Policy Statement to provide additional information regarding the path of home price variables, in particular, reducing uncertainty about the path of these variables in the severely adverse scenario. Second, the Board adopted a final Stress Testing Policy Statement to provide additional information about the Board's principles and policies with regard to supervisory stress test model development and validation.[18] As described in the Stress Testing Policy Statement, material changes to the supervisory stress test models are phased in over two years to reduce year-over-year volatility stemming from updates to the supervisory models.[19] This approach contributes to the stability of the results of the supervisory stress test by ensuring changes in model projections primarily reflect changes in underlying risk factors and scenarios, year over year. Third, the Board provided additional information about the models used in the supervisory stress test.[20] The Board is committed to continuing to provide additional information, including modeled loss rates by loan and borrower characteristics, of its stress test models as it has done most recently for its corporate loan and credit card models.[21]

Regarding the publication of scenarios for comment, the Board is considering these comments and weighing the benefit of increased transparency against the costs, including, increased risk of window-dressing by firms and reduced flexibility by the Board to respond to salient risks. Finally, the Board received no comments on the use of the severely adverse scenario to size a firm's stress capital buffer requirement, although some commenters expressed concern regarding the scope of application of additional components of the severely adverse scenario. Because these additional components capture risks that are not sufficiently captured by the macroeconomic scenario, the final rule maintains the supervisory stress test's severely adverse scenario as the basis for the calculation of a firm's stress capital buffer requirement and makes no changes to the scenario design process.

ii. Abruptness of Buffer Restrictions

In light of the proposed integration of the supervisory stress test results into the capital rule, several commenters suggested that the Board revisit the mechanics of the capital conservation buffer requirement's payout restrictions, including the definition of eligible retained income. Specifically, commenters noted the case of a relatively healthy firm in normal economic conditions that distributes the full amount of its earnings in each of the preceding four quarters, such that its eligible retained income in the current quarter is zero. Under the proposal, if such a firm's capital ratios were to immaterially fall below its buffer requirements due to an increase in its stress capital buffer requirement, that firm would have been prohibited from making any distributions. To address this issue, some commenters recommended the calculation provided under the definition of eligible retained income should be based on a firm's prior four quarters of earnings *gross* of distributions. Other commenters suggested adopting a prospective payout restriction based on earnings recognized since the end of the last quarter in which a firm failed to meet its full stress capital buffer requirement. Some commenters noted that because firms are more likely to decrease share repurchases before decreasing dividends and executive compensation, the capital conservation buffer's payout restrictions should initially restrict only repurchases, and subsequently restrict dividends and executive compensation if a firm's capital levels declined further.

The proposal would have used the current capital rule's definition of eligible retained income, which was adopted in the wake of the financial crisis when firms tended to retain a substantial portion of their earnings. Under a more benign business environment, firms tend to distribute all or nearly all of their net income, resulting in very low or zero eligible retained income and potential sudden and severe distribution limitations if a firm's capital ratio unexpectedly falls below its capital conservation buffer requirement. To reduce the potential for such a scenario, in connection with the stress capital buffer requirement, the final rule replaces the capital rule's current concept of eligible retained income with quarterly average net income—the average of a firm's previous four quarters of net income—in certain cases. Specifically, to the extent that a firm's risk-based capital ratios determined under the standardized approach exceed the minimum requirements plus 2.5 percent plus any applicable GSIB surcharge and countercyclical capital buffer amount, the firm would use quarterly average net income to determine its eligible retained income.

For example, under the final rule, if a firm has a stress capital buffer requirement of 5.5 percent, and its CET1 capital ratio falls to 3 percent above the minimum requirement, the firm would use the average of its past four quarters of net income to calculate its maximum distributable amount. However, to ensure that firms subject to the stress capital buffer requirement are not subject to a capital conservation buffer requirement that is less strict than that the requirements that apply more broadly under the current capital rule, if this firm's CET1 capital ratio falls below 2.5 percent above the minimum requirements, the firm would be required to calculate its maximum distributable amount by using the previous four quarters of net income net of any distributions and associated tax effects not already reflected in net income.

Even though income and capital ratios will not be reported on a firm's filings until later in the quarter, firms that are subject to the stress capital buffer requirement are expected to know their capital positions and be able to calculate any distribution restrictions on a daily basis. If a firm has any uncertainty regarding its quarter-end capital ratios prior to filing its regulatory reports, it should be conservative with capital distributions (including repurchases) during the beginning of a calendar quarter in order to avoid a situation in which it distributes more than the amount permitted under the capital rule. Under the final rule, all other

[16] *See* 12 CFR part 252, Appendix A.

[17] *https://www.federalreserve.gov/newsevents/pressreleases/bcreg20190205a.htm.*

[18] *See* 12 CFR part 252, Appendix B.

[19] The Policy Statement defines a model change as highly material if its use results in a change in the CET1 ratio of 50 basis points or more for one or more firms, relative to the model used in prior years' supervisory exercises. *See* 12 CFR 252, Appendix B 2.3.

[20] *See* 84 FR 6784 (February 5, 2019).

[21] *See* Board of Governors of the Federal Reserve System, Dodd Frank Act Stress Test 2019: Supervisory Stress Test Methodology (March 2019), *https://www.federalreserve.gov/publications/files/2019-march-supervisory-stress-test-methodology.pdf.*

aspects of the stress capital buffer requirement are being finalized as proposed. Moving from the current definition of eligible retained income to a quarterly average net income measure in the capital rule makes the automatic limitations on a firm's distributions more gradual as the firm's capital ratios decline.

C. Stress Leverage Buffer

The proposal would have included a stress leverage buffer requirement that would be determined based on the supervisory stress test. Some commenters urged the Board to remove the proposed stress leverage buffer requirement, noting that it could undermine the purpose of leverage-based measures to act as a simple, risk-insensitive backstop to risk-based capital requirements. These commenters were concerned that the proposed stress leverage buffer requirement would increase the probability that a banking organization's binding post-stress capital constraint would be a leverage requirement rather than a risk-based one, and would add complexity to the capital rule. One commenter suggested that if the Board adopts the proposed stress leverage buffer requirement, it should revise the capital rule such that the stress leverage buffer requirement does not result in payout restrictions, but would only prompt heightened scrutiny through the Federal Reserve's ongoing supervisory processes. Other commenters supported adopting the proposed stress leverage buffer requirement and some urged the Board to retain a post-stress capital requirement for the supplementary leverage ratio to maintain the practice of evaluating off-balance sheet exposures in the supervisory stress test.

Because leverage requirements are not risk-sensitive, the Board has long held the view that leverage ratio requirements should serve as a robust backstop to the risk-based requirements. In light of the integration of CCAR and the Board's non-stress capital requirements, which include leverage ratio requirements that serve as a backstop to the risk-based requirements, the final rule does not contain a stress leverage buffer requirement. Non-stress leverage ratio requirements continue to apply to all firms. The final rule results in unchanged CET1 capital requirements and not imposing a stress leverage buffer requirement increases the likelihood that that risk-based requirements will be the binding requirement for firms.

D. Effective Dates for Stress Capital Buffer Requirement

A firm's stress capital buffer requirement becomes effective on October 1 of each year, and remains in effect until September 30 of the following year, unless the firm receives an updated stress capital buffer requirement from the Board.[22] The final rule will be effective May 18, 2020, and a firm's first stress capital buffer requirement will be effective on October 1, 2020.[23]

IV. Changes to the Capital Plan Rule

This section describes changes to the capital plan rule. Specifically, the final rule adopts the proposal's elimination of the quantitative objection and the process by which a firm determines the final planned capital distributions included in its capital plan. As discussed below and in response to comment, under certain conditions, the final rule no longer requires a firm to request prior approval to make distributions that exceed the amount included in its capital plan. The final rule also clarifies the timeline and procedures related to a firm's stress capital buffer requirement, requests for reconsideration, and capital plan resubmissions.

A. Quantitative Objection

The proposal would have replaced the ability for the Board to object to a firm's capital plan if the firm did not demonstrate the ability to maintain capital ratios above the minimum requirements on a post-stress basis with the automatic distribution limitations included in the capital rule, which would include the firm's stress capital buffer requirement. Commenters generally were supportive of the elimination of the quantitative objection, and the final rule eliminates the quantitative objection as proposed.

One commenter requested that the Board clarify that it would not qualitatively object to a firm's capital plan based on quantitative weaknesses in the firm's capital position. As noted above, the Board adopted a final rule in March 2019 to limit the use of the qualitative objection. For those firms that remain subject to the qualitative objection in CCAR 2020, the Board will not evaluate the firm's ability to maintain capital ratios above minimum requirements on a post-stress basis as a factor in its decision to object or not object to the firm's capital plan on a qualitative basis. As proposed, in determining whether to object to a firm's capital plan, the Board will consider whether the firm has material unresolved supervisory issues, the assumptions and analysis underlying its capital plan, and the capital planning process and methodologies of the firm.

B. Requirements for a Firm's Planned Capital Distributions

To help ensure that a firm's planned capital distributions are consistent with statutory and regulatory requirements, the proposal would have required a firm to limit the planned capital distributions included in its capital plan for the fourth through seventh quarters of the planning horizon to those that would be consistent with any effective capital distribution limitations that would apply under the firm's own baseline projections (BHC baseline scenario).[24] The proposal specified that a firm would be required to plan for all limitations on capital distributions in the Board's rules, except those specifically related to the advanced approaches capital conservation buffer requirement and total loss-absorbing capacity buffer requirement calculated using the advanced approaches.[25] As discussed further in Section IV.D, the proposal would have required a firm to adjust its planned distributions to be consistent with these distribution limitations under the BHC baseline scenario, assuming the new stress capital buffer requirement applied.

The Board did not receive any comments on the requirement that firms must plan to be in compliance with the capital rules in their BHC baseline scenario projection, and the Board is adopting this aspect of the proposed rule without modification.

C. Elimination of Prior Approval

The proposal would have retained the requirement that a firm generally seek

[22] A firm may receive an updated stress capital buffer requirement in connection with a resubmitted capital plan or in connection with a request for reconsideration (as described in section IV of this preamble).

[23] To provide a transition between the 2019 CCAR cycle and the first stress capital buffer requirement, for the period from July 1 through September 30, 2020, a firm will be authorized to make capital distributions that do not exceed the four-quarter average of capital distributions for which the Board or Reserve Bank indicated its non-objection in the previous capital plan cycle, unless otherwise determined by the Board.

[24] Under the proposal, a firm would have been required to ensure its planned capital distributions were consistent with any limitations on capital distributions in effect, including those related to any applicable capital buffer requirement, that it anticipates would apply under baseline conditions under the capital rule's standardized approach in the upcoming year. However, the proposal would not have required a firm to consider planned discretionary bonus payments.

[25] *See e.g.,* 12 CFR 217.11, 12 CFR 252.63, 12 CFR 252.165, and 12 CFR part 263.

prior approval from the Board to make a capital distribution in which the dollar amount of the firm's capital distributions exceeded the amount described in its capital plan. The Board sought comment on alternative approaches to this requirement, including the advantages or disadvantages of providing additional flexibility for a firm to make capital distributions in excess of the capital distributions included in its capital plan.

Some commenters asserted that the prior approval requirement is unnecessary and duplicative in light of automatic distribution restrictions already in place in the capital rule. These commenters argued that retaining this requirement would result in undue burden on firms and would be inconsistent with the proposal's goal of simplifying the Board's capital requirements. These commenters also argued that eliminating prior approval would support flexible capital planning by allowing firms to adapt to actual capital and earnings. Other commenters were supportive of retaining the requirement. These commenters argued that providing additional flexibility to make capital distributions would further weaken capital standards by allowing firms additional leeway in making capital distributions and would be unnecessary in light of firm profitability and recent distributions.

Commenters provided a number of suggestions for allowing firms to increase their planned capital distributions without seeking approval from the Board, including eliminating the prior approval requirement altogether. For, example, some commenters supported allowing a firm to exceed the capital distributions included in its capital plan on the condition that the firm's capital ratios exceeded its BHC baseline scenario projections. Others recommended that all increases in planned capital distributions become subject to an expedited prior approval requirement, such as the process applied to de minimis capital distribution increases, or that the Board remove the ''blackout period'' during which a firm is not permitted to request prior approval. These commenters also argued that the stress capital buffer requirement should be used to satisfy prior approval requirements in the capital rule, which requires a firm to seek prior approval for redemptions and repurchases of regulatory capital instruments.[26]

After reviewing the comments, the Board has modified the proposed rule so that, as a general matter, a firm will no longer be required to request prior approval to make distributions in excess of those included in its capital plan, provided that the distribution is consistent with distribution limitations included in the capital rule. Removing the requirements to request prior approval for incremental capital distributions reduces burden, further integrates the capital plan rule and the capital rule, and provides firms with additional flexibility in capital planning. Under the final rule, firms will remain subject to the automatic distribution limitations in the capital rule, which will include a firm's stress capital buffer requirement.

While the final rule provides firms additional flexibility, the capital plan rule requires that a firm engage in capital planning. A firm's processes for managing and allocating its capital resources are critical to its financial strength and resiliency and also to the stability and effective functioning of the U.S. financial system. The capital plan rule requires a firm to develop and maintain a capital plan that includes an assessment of the sources and uses of capital and reflects forward-looking projections of revenue and losses to monitor and maintain their internal capital adequacy. A capital plan must be reviewed and approved at least annually by the firm's board of directors or a designated subcommittee thereof. The firm's planned capital actions should be consistent with the firm's capital policy, including the amounts of planned dividends and repurchases. Taken together, these requirements help ensure disciplined capital planning. In addition, a firm's capital plan and capital planning processes will continue to be reviewed through the supervisory process and, if applicable, through the qualitative objection.

The final rule also requires a firm to provide the Board and appropriate Reserve Bank with notice within 15 days after making any capital distributions in excess of those included in its capital plan. A firm would provide notice of additional distributions through an update to a firm's FR Y–14A Schedule C, Regulatory Capital Instruments. This reporting requirement will allow the Board to continue to monitor a firm's capital distributions.

Under the final rule, there remain certain circumstances under which a firm will be required to seek prior approval to distribute capital. Specifically, if a firm receives a qualitative objection to its capital plan, it would be required to seek prior approval before making any capital distributions. In addition, if a firm or the Board determines that a firm must resubmit its capital plan, the firm would be required to seek prior approval before making any capital distributions until the firm received prior approval to make distributions or receives notice regarding recalculation of its stress capital buffer requirement. Maintaining prior approval requirements in these instances is appropriate given the circumstances that would give rise to a qualitative objection or a resubmitted capital plan. In the case of a qualitative objection, the Federal Reserve has determined that the firm's capital planning processes are inadequate or unreasonable, or would constitute an unsafe or unsound practice. In the case of a resubmitted capital plan, either the firm or the Board has determined that a material change to the firm's risk profile or financial condition has occurred or will occur, which may indicate that a firm's stress capital buffer requirement no longer adequately reflects its risk profile. Finally, the final rule provides a transition provision during the quarter before the first stress capital buffer requirement is effective to permit a firm to seek prior approval for any distribution that would exceed an amount equal to the average of the capital distributions for the four quarters to which the Board previously indicated its non-objection.

With respect to the limited circumstances under which prior approval would still be required, the final rule makes certain targeted amendments to the prior approval process. Specifically, the final rule clarifies that a firm is required to submit either its current capital plan or a description of changes to its capital plan as part of its request for prior approval. This would permit the Board to consider a prior approval request in advance of receiving a resubmitted plan.[27] The final rule would not change

[26] As part of a separate final rule to simplify elements of the capital rule, the Board amended section 20 of the capital rule to remove the requirement to obtain prior approval of the Board before redeeming or repurchasing CET1 capital instruments only to the extent otherwise required by law or regulation. That final rule largely removes prior approval requirements for redemptions and repurchases of CET1 capital under the capital rule. Firms must obtain prior approval to redeem or repurchase CET1 capital only to the extent otherwise required by law or regulation, such as the requirements under section 225.4 of Regulation Y or section 11 of the Federal Reserve Act. *See* 12 CFR 217.20(f) and 84 FR 35234 (July 22, 2019).

[27] A firm must resubmit its capital plan within 30 calendar days of determining that a resubmission is required or of receiving notice that a resubmission is required. In some cases, a resubmission may be triggered by an anticipated change to the corporate structure or risk profile of the firm. By allowing the

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other aspects of the prior approval process, including other informational requirements and the Board's process for considering these requests. In considering a request for prior approval in the past, the Board has generally permitted a firm to make capital distributions that are consistent with distributions included in its capital plan.

In 2016, the Board amended the capital plan rule to include a ''blackout period,'' during which a firm was prohibited from submitting a request for prior approval to make an additional capital distribution. This requirement helped to ensure that the Board's quantitative analysis in CCAR would represent a comprehensive and current evaluation of the firm's capital adequacy. Under the final rule, the calculation of a firm's stress capital buffer requirement no longer includes capital distributions (except for dividends in projection quarters four through seven), so a request by a firm for prior approval to make an additional capital distribution would not impact the calculation of a firm's stress capital buffer requirement. In addition, given the circumstances during which prior approval will be required and the potential for a capital plan resubmission at any time of the year, a ''blackout period'' is unnecessary. Therefore and in response to comments received, the final rule removes the ''blackout period'' for additional capital distribution requests.

D. Timeline for Reviewing Capital Plans and Calculating the Stress Capital Buffer Requirement

The proposal included an updated timeline for the capital plan cycle under the stress capital buffer framework. The proposal maintained the Board's timeline for providing a firm with the results of the supervisory stress test and review of its capital plan. Under the proposal, a firm would have received notice of its stress capital buffer requirement by June 30 of each year.

Some commenters expressed concerns regarding the effective date of a stress capital buffer requirement, which are discussed in Section III.D.

The final rule generally adopts the timeline as proposed. Under the final rule, the as-of date for the capital plan cycle will be December 31 of the previous calendar year, and the planning horizon for capital planning will be a period of nine consecutive quarters from that date. Firms will generally submit their capital plans and related regulatory reports by April 5. The Board will generally determine each firm's stress capital buffer requirement in the second quarter of the year (April through June).[28] By June 30, the Board generally will disclose to the public each firm's stress capital buffer requirement.

Commenters requested further clarity regarding public disclosure of the stress test results and stress capital buffer requirements. Some commenters requested that the Board disclose only one set of results. Other commenters expressed concerns regarding public disclosure of planned dividends and requests for reconsideration. The final rule clarifies, but does not require, that the Board to disclose of certain types of information. Consistent with current practice, the Board anticipates disclosing summary information regarding a firm's stress losses.[29] The Board may consider additional changes to further streamline its stress testing disclosure practices.

The final rule will not be effective before a firm is required to submit its capital plan and the results of its company-run stress test, if applicable, for the 2020 stress testing cycle. The final rule will be effective prior to the Board conducting the supervisory stress test. Accordingly, the results of a company-run stress test will reflect different assumptions, particularly regarding capital actions and material business plan changes, than would be used as part of the supervisory stress test. A firm will be required to disclose the results of its company-run stress test within 15 days of the Board disclosing the results of the supervisory stress test. The Board intends to clarify in its disclosures for 2020 that the assumptions used in the supervisory stress test are different from the assumptions used in the company-run stress tests for 2020 and, therefore, the results are not comparable.

Under the proposal, within two business days of receipt of notice of its stress capital buffer requirement, a firm would have been required to assess whether its planned capital distributions are consistent with the effective capital distribution limitations under the BHC baseline scenario throughout the fourth through seventh quarters of the planning horizon, assuming that the firm's new stress capital buffer requirement replaced any existing stress capital buffer requirement. In the event of an inconsistency, a firm would have been required to reduce the capital distributions in its capital plan to be consistent with such limitations for those quarters of the planning horizon.[30] A firm would have been required to notify the Board of any reductions in capital distributions in its capital plan (adjustment process).

Some commenters expressed concerns regarding the adjustment process. These commenters argued that modifications to the adjustment process were necessary to support flexible capital planning in light of variability in the supervisory stress test, particularly if the Board retained dividend add-on or prior approval requirements. For example, some commenters requested that firms be permitted to increase planned issuances in order to meet the requirements in the BHC baseline scenario projections and to allow planned increases in capital distributions.

In response to comments, the Board has revised this process in the final rule to allow firms to make any adjustments to their planned capital distributions during the two-day adjustments process, provided that the revised planned capital distributions are consistent with the effective capital distribution limitations that would apply on a pro forma basis under the BHC baseline scenario throughout the fourth through seventh quarters of the planning horizon. Allowing a firm to increase its planned distributions would provide firms additional flexibility in capital planning, including by allowing firms to reflect the results of the supervisory stress test. Any increases in planned dividends in quarters four through seven of the planning horizon would be reflected in a firm's stress capital buffer requirement.

Each firm's updated annual stress capital buffer requirement generally will become effective on October 1 and be in effect until September 30 of the

Federal Reserve to consider a prior approval request in advance of receiving a resubmitted plan, the final rule would provide the Board additional flexibility to consider and act on a request based on a discussion of the changes to the capital plan rather than receipt of the capital plan. Consistent with past practice, a firm would be able to incorporate by reference portions of its previously filed capital plan to the extent that those portions are unaffected by the change requiring submission.

[28] For firms subject to a potential qualitative objection, the qualitative assessment will take place from April to June. By June 30, the Board generally will disclose the decision to object or not object to the capital plan of any firm subject to a qualitative objection.

[29] As discussed further in Section IV.E. and IV.F., a firm may request reconsideration of its stress capital buffer requirement and the Board may recalculate a firm's stress capital buffer requirement if a firm resubmits its capital plan. In the event that a firm receives a revised stress capital buffer requirement, a firm would be required to disclose its revised stress capital buffer requirement and its buffer on the FR Y–9C form.

[30] In addition, a firm that is not required to reduce its planned capital distributions will be permitted to do so after receiving its initial notice.

following calendar year. Table 1 below summarizes key actions and the dates that these actions generally will occur in the annual capital plan cycle under the final rule.

TABLE 1—KEY DATES AND ACTIONS IN THE ANNUAL CAPITAL PLAN CYCLE

Date	Action
December 31 of the preceding calendar year.	As-of date of the capital plan cycle.
By February 15	Board publishes scenarios for the upcoming capital plan cycle.
By April 5	Each firm submits its capital plan (including results of the bank holding company's stress tests) and relevant regulatory reports.
April through June	Board conducts its supervisory stress test and calculates each firm's stress capital buffer requirement.
By June 30	The Board provides to a firm notice of its stress capital buffer requirement. A firm will have 15 days to make a request for reconsideration.
Within two business days of notice.	Each firm must analyze its planned capital distributions for the period of October 1 through September 30 of the following calendar year, adjust its planned distributions if necessary, and provide the Board its final planned capital distributions.
October 1 through September 30 of the following calendar year.	Effective dates of a firm's stress capital buffer requirement.

The Board's previous review and approval of planned capital actions covers the four-quarter period between July 1 of each year and June 30 of the following calendar year. The stress capital buffer requirement becomes effective on October 1, 2020. As a result, a firm will not have any approved planned capital actions for the period July 1 to September 30, 2020. To provide a transition to the stress capital buffer requirement, the final rule authorizes a firm to make capital distributions for the period July 1 to September 30, 2020, that do not exceed a four quarter average of capital distributions to which the Board indicated its non-objection for the previous capital plan cycle, unless otherwise determined by the Board. A firm may seek prior approval to make additional capital distributions beyond this four-quarter average amount using the prior approval process discussed in Section IV.C.

E. Requests for Reconsideration

The proposed rule would have modified the process for requesting reconsideration of an objection to a capital plan and extended this process to include the ability to request reconsideration of the stress capital buffer requirement. Under the proposal, a firm that requested reconsideration of its stress capital buffer requirement would have been required to submit a request to the Board in writing within 15 days of receipt of the firm's stress capital buffer requirement, and the Board would have responded in writing within 30 days. The firm's request would have been required to include an explanation of why the firm believes that its stress capital buffer requirement should be reconsidered.

The proposed procedures were intended to provide a firm with an opportunity to respond to its stress capital buffer requirement or a qualitative objection to its capital plan, and to help ensure that the stress capital buffer requirement is appropriately sized and that the Board has considered all relevant aspects of the firm's capital planning and capital adequacy process. Some commenters argued that the proposed timeline for the reconsideration process should be extended, asserting that the proposed October 1 effective date of the stress capital buffer requirement would provide insufficient time to prepare for changes in capital requirements and, as a result, reduce the usefulness of the reconsideration process. These commenters argued that a firm would be required to prepare for a stress capital buffer requirement during the pendency of a request for reconsideration, reducing the value of the reconsideration process.

The final rule maintains the proposed reconsideration process and timeline without modification. This process is based on the process that has been included in the capital plan rule since its adoption in 2011.[31] The reconsideration process is intended to provide the firm with a meaningful opportunity to request reconsideration of the stress capital buffer requirement or objection to a capital plan, including through the presentation of additional information, while promoting an efficient process. In particular, the timeline is intended to provide an opportunity for response, while ensuring that the results of the supervisory stress test and a firm's most recent capital plan are reflected in the firm's ongoing capital requirements and planned distributions as quickly as possible. Prolonging the period for requesting reconsideration or responding to a request for reconsideration also would delay incorporation of more current information about a firm's risk profile that are not contested, including its balance sheet, into the firm's stress capital buffer requirement or capital plan. In addition, the final rule provides that the Board may extend the time for acting on a request for reconsideration, which would allow the Board to request and the firm to submit additional information or delay the effective date of a stress capital buffer requirement, if needed. Finally, as discussed in Section III.B the Board has adopted changes to its stress testing framework to increase transparency and certainty. By providing greater transparency and predictability, these changes also may reduce the likelihood that a request for reconsideration is made.

The capital plan rule provides that a firm that requests reconsideration of an objection to its capital plan may request an informal hearing as part of its request for reconsideration. The Board, in its sole discretion, may order an informal hearing if the Board finds that a hearing is appropriate or necessary to resolve issues of fact raised in the request for recommendation. The proposal would have extended this option to requests for reconsideration of a stress capital buffer requirement. The Board did not receive comments on the informal hearing procedures provisions as applied to the stress capital buffer requirement. Thus, the final rule provides firms with an opportunity to request an informal hearing as part of

[31] 76 FR 74631 (December 1, 2011).

their request for reconsideration of either an objection to a capital plan or a stress capital buffer requirement.

F. Capital Plan Resubmission and Circumstances Warranting Recalculation of the Stress Capital Buffer Requirement

The proposal would have maintained the circumstances under which a firm was required to resubmit a capital plan and the process for reviewing a resubmitted capital plan. In particular, the Board could have required a firm to resubmit its capital plan if the Board determines that there has been a material change in the firm's risk profile, financial condition, or corporate structure or if the bank holding company stress scenario(s) used in the firm's most recent capital plan are no longer appropriate for the firm's business model and portfolios, or if changes in financial markets or the macro-economic outlook that could have a material impact on a firm's risk profile and financial condition require the use of updated scenarios (material change). Additionally, a firm would have been required to resubmit its capital plan if it determines there has been or will be a material change since the firm last submitted its capital plan to the Board.

The proposal would have integrated the existing resubmission process with the stress capital buffer requirement by permitting the Board to recalculate a firm's stress capital buffer requirement if the firm chose to or was required to resubmit its capital plan. Under the proposal, the Board would have reviewed a resubmitted capital plan within 75 calendar days after receipt and, at the Board's discretion, provided the firm with an updated stress capital buffer requirement. Upon a determination that a firm has had a material change in its risk profile, the Board could have conducted an updated supervisory stress test and recalculated the firm's stress capital buffer requirement based on the resubmitted capital plan.[32] As with the process for submitting the annual capital plan, the planned capital distributions in the firm's resubmitted capital plan would have been required to be consistent with any capital distribution limitations that would have applied on a pro forma basis over the planning horizon. Any updated stress capital buffer requirement would have been in effect until the firm's updated stress capital buffer requirement from the next annual assessment by the Board became effective (unless the firm experienced another material change prior to that date).

Some commenters supported the inclusion of a process to recalculate a firm's stress capital buffer requirement, but expressed concern about the circumstances under which a stress capital buffer requirement would be recalculated as well as the methodology for recalculation. In particular, some commenters expressed concern regarding the proposed approach of recalculating a firm's stress capital buffer requirement based on a resubmitted capital plan. One commenter argued that recalculation of a stress capital buffer requirement based on a resubmitted plan would discourage a firm from resubmitting a capital plan. Some commenters urged the Board to separate the process for recalculating a stress capital buffer requirement from resubmission of a capital plan, suggesting instead that recalculation of the stress capital buffer requirement be made at the option of the firm or automatically based on information reported on the FR Y–14 reports. Other commenters expressed concern regarding the methodology for recalculation, asserting that recalculation based on a new or different stress scenario could produce a significantly different stress capital buffer requirement. Finally, some commenters expressed concerns about the resubmission process generally, including the distribution limitations on firms that resubmit a capital plan as well as the circumstances under which a resubmission would be required.

The final rule adopts the proposed process for recalculating a firm's stress capital buffer requirement based on a resubmitted capital plan.[33] The circumstances that require a firm to resubmit its capital plan may also indicate that its stress capital buffer requirement no longer reflects its risk profile. Accordingly, the automatic distribution limitations that would apply if the firm held capital within its buffer also may not be sufficient. As commenters observed, a firm may resubmit a capital plan for a variety of reasons. Not every change to a firm's capital plan or balance sheet would be significant enough to warrant recalculation of its stress capital buffer requirement. In some cases, a capital plan may be resubmitted based on anticipated changes in the corporate structure or business of the firm, and a stress capital buffer requirement may be more accurately evaluated after consummation of the anticipated change. Accordingly, the final rule provides the Board discretion in determining when and how to recalculate a stress capital buffer requirement based on a resubmitted capital plan. If a firm resubmits its capital plan, the Board will inform the firm of whether its stress capital buffer requirement will be recalculated within 75 days of the capital plan being resubmitted. In response to concerns regarding the restrictions on distributions triggered by a resubmission, as discussed in Section IV.C., the final rule would simplify and clarify the submission requirements for prior approval requests made as a result of a resubmitted capital plan. The final rule also would maintain the criteria for resubmission of a capital plan based on a material change. These criteria help support an effective capital planning process.

V. Changes to the Capital Rule and Mechanics of Distribution Limitations

Under the capital rule, a firm is subject to restrictions on distributions and discretionary bonus payments if the firm's capital ratios are at or below its minimums plus its capital conservation buffer requirement.[34] For all firms, the capital conservation buffer requirement is composed of CET1 capital and is equal to 2.5 percent of risk-weighted assets, plus any applicable countercyclical capital buffer amount and GSIB surcharge.

To incorporate the stress capital buffer requirement into the capital rule, the proposal would have revised the capital rule to include the stress capital buffer requirement in the capital conservation buffer framework. A firm would have been subject to the most stringent distribution limitation, if any, as determined by the firm's standardized approach capital conservation buffer requirement, the firm's stress leverage buffer requirement and, if applicable, the firm's advanced approaches capital conservation buffer requirement, and the enhanced supplementary leverage ratio standard.[35] A firm's standardized

[32] For this purpose, the planning horizon would have been the nine quarter period beginning on the date after the as-of date of the projections. For instance, if the as-of date of the projections was June 30, 2020, the planning horizon would have extended from July 1, 2020, through September 30, 2022.

[33] The final rule also would maintain the process for reviewing a resubmitted capital plan for a firm subject to the qualitative objection.

[34] *See* 12 CFR 217.11.

[35] Consistent with the proposal, the final rule does not alter the substance of the buffer applicable to GSIBs under the Board's enhanced supplementary leverage ratio standards. The regulatory language implementing this buffer is revised by the final rule to integrate the enhanced

approach capital conservation buffer requirement would have been equal to the sum of: (1) Its stress capital buffer requirement as calculated using the standardized approach, (2) as applicable, the firm's GSIB surcharge; and, (3) as applicable, the firm's countercyclical capital amount.[36] A firm's advanced approaches capital conservation buffer requirement would have been equal to the sum of: (1) 2.5 percent of risk-weighted assets calculated using the advanced approaches, (2) as applicable, the firm's GSIB surcharge; and, (3) as applicable, the firm's countercyclical capital buffer amount. Similarly, under the proposal, a firm would have compared its leverage buffer to its stress leverage buffer requirement.

Under the proposal, a firm would have been subject to the most stringent distribution limitation as determined by the firm's standardized approach capital conservation buffer requirement, the firm's stress leverage buffer requirement and, if applicable, the firm's advanced approaches capital conservation buffer requirement, and the enhanced supplementary leverage ratio standard. A firm would have determined the maximum amount it could pay in capital distributions and discretionary bonus payments during a given quarter by multiplying the firm's eligible retained income by its applicable payout ratio, if any, as determined under Table 2 to 12 CFR 217.11 of the proposed rule.

Several commenters supported the proposal to separate the standardized approach capital conservation buffer and the advanced approaches capital conservation buffer and to only incorporate the stress capital buffer requirement into the standardized approach capital conservation buffer. Arguments in favor of not incorporating the stress capital buffer requirement into the advanced approaches capital conservation buffer generally focused on the complexity such an approach would add to the rule by combining two different model-based approaches (*i.e.,* the advanced approaches and the stress test). However, some commenters supported applying the stress capital buffer requirement over advanced approaches risk-weighted assets by scaling the stress capital buffer requirement by the ratio of a firm's standardized risk-weighted assets to its advanced approaches risk-weighted assets.

Some commenters argued that the stress capital buffer requirement would remove the need for firms to calculate risk-weighted assets using the advanced approaches because both effectively measured capital needs based on a firm's internal risk-based methodologies. These commenters recommended removal of the advanced approaches from the capital rule altogether, or that the Board narrow the scope of the advanced approaches to only the largest, most systemic firms. Some commenters also supported removing the advanced approaches from the capital rule for reasons unrelated to this rulemaking.

The final rule includes the buffer framework with certain revisions from the proposal. Most notably, the final rule includes a revised definition of eligible retained income and does not include the proposed stress leverage buffer.[37]

As discussed in the proposal, the interaction of the stress capital buffer requirement and a firm's risk-based capital ratios calculated using the advanced approaches would add excessive complexity to the rule, whether through the use of a scaling factor or other calibration adjustment. Consistent with the rationale in the proposal, the final rule does not incorporate the stress capital buffer requirement into the advanced approaches capital conservation buffer.

The Board is not removing the advanced approaches from the capital rule in this final rule. The concerns related to the interaction of the advanced approaches and the stress capital buffer requirement are addressed in the final rule by limiting the application of the stress capital buffer requirement to the standardized approach capital requirements. The Board continues to believe that large and more systemic firms should be subject to more risk-sensitive capital requirements commensurate with their risk profiles.

Some commenters supported the Board's proposal to include any applicable countercyclical capital amount in the capital conservation buffer requirement, noting that it is not redundant with the stress capital buffer requirement, as each addressed different risks independently. Other commenters argued that the stress capital buffer requirement could make the countercyclical capital buffer redundant, and recommended that the Board make only sparing use of the countercyclical capital buffer. Some commenters urged the Board to remove the countercyclical capital buffer from the capital rule, arguing that it was fully redundant with the stress capital buffer requirement due to countercyclical features of the stress tests. Commenters also argued that countercyclical capital requirements could be set more effectively through the stress capital buffer requirement than the countercyclical capital buffer. Commenters also argued that, if the countercyclical capital buffer were retained, any activation of the countercyclical capital buffer should be reflected in the stress testing framework.

Consistent with the proposal, the final rule retains the countercyclical capital buffer as a tool the Board could use to address situations when systemic vulnerabilities are meaningfully above normal. The stress capital buffer requirement is not redundant with the countercyclical capital buffer. The countercyclical capital buffer is a macroprudential tool intended to strengthen the resiliency of financial firms and the financial system, by allowing the Board to raise capital standards when credit growth in the economy becomes excessive. The Board's stress testing scenario design framework is designed to mitigate the inherent procyclicality in the stress test, not to serve as an explicit countercyclical offset to the financial system. As a result, there may be circumstances where the countercyclical capital buffer is the appropriate tool to address systemic vulnerabilities, and it is important to retain this tool as a potential option going forward.

One commenter urged the Board to recognize the ability of long-term debt issued under the Board's Total Loss-Absorbing Capacity (TLAC) rule to absorb losses in the same manner as common equity tier 1 capital. The commenter therefore recommended that firms be permitted to satisfy all or a portion of the stress capital buffer requirement with internal long-term debt or common equity tier 1 capital.

Only a subset of firms subject to the capital plan rule are subject to the TLAC rule—U.S. GSIBs and the U.S. intermediate holding companies of non-U.S. GSIBs—and these firms are among the larger and more systemic firms subject to the capital plan rule. Providing these firms with greater flexibility to satisfy the buffers would be inconsistent with the general principle that larger and more systemic firms

supplementary leverage ratio buffer with the stress capital buffer requirement within the capital rule.

[36] The existing buffer framework in the capital rule would have remained unchanged for firms not subject to the capital plan rule.

[37] The revisions to eligible retained income are discussed in greater detail in Section III.A and the stress leverage buffer requirement is discussed in greater detail in Section III.D.

should be subject to more stringent and risk-sensitive requirements. In addition, the loss-absorbing capacity of long-term debt issued under the Board's TLAC rule is not identical to the loss-absorbing capacity of CET1 capital as the way in which long-term debt could absorb losses varies by circumstance. As a result, the Board is maintaining the requirement that the standardized approach capital conservation buffer and the advanced approaches capital conservation buffer must be satisfied with common equity tier 1 capital.

Several commenters raised concerns that the stress capital buffer requirement would be redundant with the GSIB surcharge. Some commenters noted that both the stress capital buffer requirement and GSIB surcharge account for risks arising from capital markets activities and for counterparty risks.

One commenter suggested that the Board address the potential double-counting of risks by making the stress capital buffer requirement an alternative to the current capital conservation buffer requirements. Specifically, the commenter suggested that a firm's buffer requirement be the greater of (1) its stress capital buffer requirement, and (2) 2.5 percent, plus any applicable GSIB surcharge and countercyclical capital buffer amount. Other commenters suggested additional similar structures for a firm's buffer requirement. Commenters asked that the Board exclude the GSIB surcharge from the standardized approach capital conservation buffer, pending revisions to the Board's GSIB surcharge rule.

The final rule, consistent with the proposal, establishes the buffer requirement for the standardized approach capital conservation buffer equal to a firm's stress capital buffer requirement, plus any applicable GSIB surcharge and countercyclical capital buffer amount. The stress capital buffer requirement, which will incorporate losses from the global market shock and the large counterparty default component, is not duplicative of the GSIB surcharge. The stress capital buffer requirement is calculated based on each firm's vulnerability to adverse economic or financial market conditions. The global market shock measures the trading mark-to-market losses associated with sudden changes in asset prices, and the large counterparty default scenario component measures the risk of losses due to an unexpected default of the counterparty whose default on all derivatives and securities financing transactions would generate the largest stressed losses for a firm. These components of the supervisory stress test do not capture the potential adverse impact of the failure of a GSIB on the financial system as a whole, which is captured only by the GSIB surcharge.

Several commenters also raised concerns regarding the methodologies used to determine the GSIB surcharge. Some commenters favored the elimination of the GSIB framework's Method 1 score, while other commenters favored the elimination of the Method 2 score. In addition, commenters raised concerns with specific GSIB indicators' ability to capture systemic risk and recommended changes to the indicators. Several commenters also made recommendations on ways to recalibrate the GSIB surcharge, such as revisiting the calibration of Method 2 in light of post-crisis reforms. Others suggested updates to the GSIB surcharge coefficients and denominators. A commenter also recommended that the Board introduce a more gradated surcharge scale to avoid potential cliff effects. Commenters urged the Board to make changes to the GSIB surcharge methodologies effective concurrently with the effective date of the stress capital buffer requirement.

The Board is not revising the GSIB surcharge rule in connection with the final rule. As noted, the GSIB surcharge is designed to address risks that differ from those addressed by the stress capital buffer requirement. As discussed in the preamble to the final GSIB surcharge rule, the GSIB surcharge, including the amount of the surcharges and the calculation of Method 1 and Method 2 scores, is designed to address the risks to the financial system presented by systemically important firms.

Taken together, the components of a firm's buffer requirements each serve independent functions. Specifically, the stress capital buffer requirement ensures that a firm has sufficient capital to continue to serve as a financial intermediary during stress. The GSIB surcharge ensures that a GSIB internalizes the cost that its failure would have on the broader economy. The countercyclical capital buffer ensures capital when there is an elevated risk of above-normal losses. For these reasons, the stress capital buffer requirement, as adopted in the final rule, serves as an appropriate complement to the other capital buffers and the GSIB surcharges.

The proposal would not have amended the current definitions of ''distribution'' and ''capital distribution'' found in the capital rule and capital plan rule, respectively.[38] Unlike the definition of distribution in the capital rule, the definition of capital distribution in the capital plan rule does not provide an exception for distributions accompanied by an offsetting issuance. The broader definition included in the capital plan rule ensures that all distributions, including those offset by issuances, are included in a firm's capital plan. However, because distributions offset by equivalent issuances within a quarter do not affect a firm's capital position, this type of distribution is not included in the definition in the capital rule. As discussed in Section IV.C, some commenters raised concerns regarding these differing definitions in the context of their recommendation to eliminate the prior approval requirement to make incremental capital actions. As the final rule eliminates the prior approval requirement, the Board is adopting this aspect of the proposal without modification and will continue to monitor this issue.

VI. Changes to the Stress Test Rules

The proposal would have revised the capital action assumptions in the Board's supervisory stress test and the company-run stress tests conducted under Regulation YY, in order to harmonize the publicly disclosed supervisory and company-run stress test results with the stress capital buffer requirement.[39] The proposal would not have included the four quarter dividend add-on in the required capital actions in the stress test rules.

The Board received several comments on the capital distribution assumptions, which were addressed above in Section

[38] Under the capital rule, the definition of distribution includes reductions in tier 1 capital through a repurchase or any other means, except when the institution, in the same quarter as the repurchase, fully replaces the tier 1 instrument by issuing a similar instrument. Under the capital plan rule, a capital distribution means a redemption or repurchase of any debt or equity capital instrument, a payment of common or preferred stock dividends, a payment that may be temporarily or permanently suspended by the issuer on any instrument that is eligible for inclusion in the numerator of any minimum regulatory capital ratio, and any similar transaction that the Board determines to be in substance a distribution of capital.

[39] In the proposal, a firm's company-run stress test, would no longer include in their capital action assumptions: (1) Actual capital actions for the first quarter of the planning horizon; (2) any common stock dividends; or (3) issuance of common or preferred stock relating to expensed employee compensation. For the first quarter of the planning horizon, firms will include any payments on any other instrument that is eligible for inclusion in the numerator of a regulatory capital ratio equal to the stated dividend, interest, or principal due on such instrument during the quarter. The capital action assumptions used in the company-run and supervisory stress tests will not include the four quarters of planned dividends.

III.B.i; however, there were no comments on the proposal to ensure that the capital actions in the company-run stress test rule matched the capital actions in the calculation of the stress capital buffer requirement. Therefore, the final rule adopts changes to the capital action assumptions in the Board's supervisory stress test and company-run stress test to be consistent with one another. [40]

As discussed above in Section III.B.i, the final rule does not include a planned material business plan change (*e.g.* merger, acquisition, or divestiture) in a firm's stress capital buffer requirement. In order to harmonize the publicly disclosed supervisory and company-run stress test results with the stress capital buffer requirement, the final rule removes the requirement to include issuances in connection with a planned merger or acquisition to the extent that the merger or acquisition is reflected in the covered company's pro forma balance sheet estimates. Consistent with current requirements, the final rule will continue to require a firm to include in its capital plan a discussion of any expected changes to the firm's business plan that are likely to have a material impact on the capital adequacy or liquidity position of the firm. Firms will continue to be expected to include the impact of a material business plan change on the FR Y–14A reports, including the Schedule A—Summary, Schedule C—Regulatory Capital Instruments, and Schedule F—Business Plan Changes.

The proposal would have incorporated the definition of ''significant trading activity'' into the Board's company-run stress test requirements in order to increase transparency regarding the application of an additional trading and counterparty scenario component.[41] Currently, significant trading activity is defined by reference to the Capital Assessments and Stress Testing report (FR Y–14Q). The FR Y–14Q defines a firm with significant trading activity as any domestic bank holding company or U.S. intermediate holding company that is subject to supervisory stress tests and that (1) has aggregate trading assets and liabilities of $50 billion or more, or aggregate trading assets and liabilities equal to 10 percent or more of total consolidated assets, and (2) is not a ''large and noncomplex firm'' under the Board's capital plan rule. The proposal would have adopted this FR Y–14 definition of significant trading activity in the stress test rules for the annual company-run stress test. Commenters did not comment on this aspect of the proposal and it is finalized as proposed.

While the Board's scenario design framework was not part of the proposal, commenters raised issues with the severity and plausibility of the supervisory scenarios. Some commenters argued that the Board's scenario design process resulted in scenarios that were implausibly severe and required firms to hold more capital than would be necessary to withstand stressful conditions. Commenters suggested that the Board introduce limits on the overall severity of the severely adverse scenario, as they argue that supervisory scenarios were more severe than historical experience. Another suggestion was to introduce a rule for scenario plausibility, including modifying the global market shock to make it more realistic and to ensure that the macroeconomic scenario is consistent with the global market shock.

As described in Appendix A to 12 CFR part 252, severely adverse scenarios are designed to be plausible, relevant, and guided in large part by historical experience in severe U.S. recessions.[42] By design, the severity of the scenarios is meant to mimic past recessions and financial crises with the addition of certain salient risks in order to ensure that firms can withstand stress and continue to lend. In addition, the Board may factor in particular risks to the scenario to make appropriate adjustments to the paths of specific economic variables that are historically less typical in order to highlight systemic risks. A comparison of the severity of recent CCAR scenarios to benchmarks in past recessions or financial crises, both domestic and international, suggests that the scenarios used in the 2017 through 2019 CCAR assessments are plausibly severe. As in the current supervisory post-stress capital assessment in CCAR, under the proposal, the supervisory stress test will continue to use a common set of scenarios, models, and assumptions across firms.

Commenters also suggested that the Board enhance the transparency of the models used in the supervisory stress test by publishing model specifications for comment, or publishing its methodology for comment each year. One commenter opposed providing more information about supervisory models or publishing the model specifications for comment. The commenter suggested such publication could lead to firms adopting stress test models that are similar to the supervisory models, potentially causing models to have common weaknesses that create risks to financial stability.

While the Board's methodology for conducting the supervisory stress test was not part of the proposal, the Board received several comments regarding the Board's models and methodology for conducting the supervisory stress test. Many of the comments focused on the assumptions associated with the global market shock and large counterparty default scenario component. These commenters' recommended reflecting the impact of the global market shock in capital deductions, reflecting variation margin in counterparty losses, capping trading losses and associated capital deductions at the total amount of a firm's trading exposure, and eliminating the double-counting of losses between the global market shock and the macroeconomic scenario. Other comments focused on other supervisory models, such as suggesting that the supervisory net income projections should reflect firm-specific considerations, such as tax attributes and that the FR Y–14 should collect credit risk mitigation transactions so that the Federal Reserve could reflect these transactions in its projections. Finally, commenters suggested that the Federal Reserve consider the impact of incorporating the current expected credit loss (CECL) methodology into the supervisory stress test.[43]

Since the Board issued the proposal in 2018, the Board separately has taken steps to respond to these comments. For example, in February 2019, the Board adopted a final stress test policy statement, which reduced the materiality threshold for phasing-in material model changes.[44] Additionally, in order to address the suggestion to reflect the impact of the global market shock on regulatory capital deductions, the Board will begin collecting information regarding this impact on the FR Y–14A starting in CCAR 2020. Similarly, the Board will also begin collecting more granular information related to tax attributes on the FR Y–14A starting in CCAR 2020, to further understand the impact of tax related items under stress.

Regarding CECL, the Board has met with various affected parties, including firms subject to the supervisory stress test, and has determined to maintain the current modeling framework for loan

[40] The supervisory and company-run stress tests conducted under Regulation YY will not include four quarters of planned dividends.

[41] *See* 12 CFR part 252, subpart F.

[42] See 12 CFR part 252, Appendix A.

[43] *See* ASU 2016–13, ''Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments.''

[44] *See* 12 CFR part 252, Appendix A.

allowances in its supervisory stress test through 2021.[45] The Board continues to consider how to implement CECL in its stress testing methodology and will continue to seek feedback on the best way to implement CECL in stress testing.

VII. Impact Analysis

The Board analyzed the impact of the final rule on the capital requirements of affected firms. This analysis compared the capital required to avoid limitations on capital distributions under the current framework and under the final rule.[46] In addition, the impact analysis considered the potential effects of the rule on economic activity.

The Board used data from the 2013 to 2019 CCAR exercises to obtain a through-the-cycle view of the impact of the rule.[47] While 2013 to 2019 represents a period of generally favorable economic and financial conditions, capital distributions—a key driver of the impact of the rule relative to current requirements—varied cyclically, rising from a relatively low level in 2013 to a high level in 2019. The impact of the rule will also vary through the economic and credit cycle based on the risk profile and planned capital distributions of individual firms, as well as on the specific severely adverse stress scenario used in the supervisory stress test.

Based on data from CCAR 2013 to CCAR 2019, the rule is estimated to result in largely unchanged CET1 capital requirements: CET1 capital requirements are estimated to increase, on average, by $11 billion, a one percent increase from current requirements. As such, viewed through-the-cycle, the rule preserves the current requirements for the highest quality capital. Looking across CCAR years, the impact of the proposal on CET1 capital requirements ranges from a decline of $59 billion to an increase of $78 billion.

The Board expects that the impact of the rule would vary for GSIBs relative to the smaller and less complex firms that are subject to the stress capital buffer requirement. On average, from 2013 to 2019, the rule is expected to lead to an increase in CET1 capital requirements for GSIBs of $46 billion, a seven percent increase in their current aggregate CET1 capital requirement. By contrast, the CET1 capital requirements for firms subject to Category II–IV standards are expected to decrease by $35 billion, a 10 percent decrease relative to their current aggregate requirement. While the less stringent balance sheet and distribution assumptions in the supervisory stress test lower capital requirements for all firms, the increased requirement for GSIBs results from the integration of a stress test-based capital requirement with each firm's GSIB surcharge.[48]

In part due to an elimination of the stress leverage buffer requirement, the rule is estimated to lower aggregate tier 1 capital requirements by $49 billion, based on average CCAR results from 2013 to 2019, a four percent decrease relative to aggregate current tier 1 capital requirements.[49] Modified balance sheet and distribution assumptions in the supervisory stress test also contribute to the decline. On average, the tier 1 capital requirement for GSIBs, the riskiest and most systemically important firms, remains unchanged by the final rule. The tier 1 capital requirements for firms subject to Category II–IV standards is expected to decrease by $49 billion, a 12 percent decrease relative to their current aggregate requirement. Looking across CCAR years, the impact of the rule would range from an aggregate reduction in tier 1 capital requirements of $102 billion to an aggregate increase in tier 1 capital requirements of $77 billion.

As the final rule has differential effects depending on the required form of regulatory capital, the Board studied the effect on overall bank funding costs to provide another view of the impact of the rule. The Board expects that the rule would slightly reduce the yearly dollar funding costs of capital and long-term debt needed to meet requirements. The changes in CET1 and tier 1 capital requirements drive these funding cost impacts.

Firms often maintain ''management buffers'' of tier 1 and CET1 capital that exceed regulatory requirements. As the final rule significantly changes how stress tests factor into capital requirements, firms may change their approach to management buffers in response to the rule. Such a change could lead to changes in levels of capital that differ from the changes in requirements reported above.

The Board examined the impact of the rule on risk sensitivity, as stress losses will determine capital requirements only for firms above the stress capital buffer requirement floor. Combining firm-by-firm data across supervisory stress test exercises from 2013 to 2019, the Board estimated that about half of the observations would have a stress capital buffer requirement above 2.5 percent. In comparison, about 90 percent of the observations in past CCAR exercises, which included the prior capital distribution assumptions and growing balance sheets, experienced capital declines of greater than 2.5 percent.

The Board also assessed the macroeconomic consequences of the final rule using models that consider the benefit of higher amounts of regulatory capital in reducing the frequency of financial crisis versus the cost of reduced lending.[50] Based on the estimated change in average capital requirements through the cycle, the proposal is expected to have little to no impact on the long-run level of GDP.

VIII. Changes to Regulatory Reports

The proposal would have modified the Consolidated Financial Statements for Holding Companies Report (FR Y–9C; OMB: 7100–0128) to collect information regarding the stress capital buffer requirement applicable to a firm and the Capital Assessments and Stress Testing Report (FR Y–14A; OMB No. 7100–0341). Specifically, the proposal would have added new line items to the quarterly FR Y–9C in order to collect information regarding a firm's stress capital buffer requirement, stress leverage buffer requirement, and GSIB surcharge and countercyclical capital

[45] *See* Board of Governors of the Federal Reserve System, ''Statement on the current expected credit loss methodology (CECL) and stress testing'' December 21, 2018, available online at: *www.federalreserve.gov/newsevents/pressreleases/files/bcreg20181221b1.pdf.*

[46] The analysis made certain simplifying assumptions. For example, the Board assumed the impact of the flat balance sheet assumption on projected losses and revenue in the stress test offset each other but included the impact of the assumption on the denominator of the projected capital ratios.

[47] Firms were subject to a CET1 capital requirement over the entire planning horizon of the supervisory stress test beginning with the 2015 CCAR exercise. For the 2013 and 2014 CCAR exercises, tier 1 common equity capital serves as a proxy for CET1 capital and is broadly similar to CET1 but includes fewer deductions, among other differences. The supervisory stress test began in 2013.

[48] The fact that the required capital as measured by Board's stress tests typically acts as the most binding capital requirement in the current framework for many GSIBs reduces the impact of incorporating the GSIB surcharge to the stress capital buffer requirement, which is currently not included in the minimum capital standards in the stress tests.

[49] Common equity tier 1 capital was developed after the financial crisis and consists of the highest quality regulatory capital. Prior to the financial crisis, tier 1 capital, which consists of common equity and non-cumulative perpetual preferred stock, was the main measure of capital adequacy.

[50] *See* Firestone, S., A. Lorenc and B. Ranish, 2019, *An empirical economic assessment of the costs and benefits of bank capital in the United States,* Federal Reserve Bank of St. Louis Review, 101, pp. 203–230; and Basel Committee on Banking Supervision, 2010, *An assessment of the long-term economic impact of stronger capital and liquidity requirements,* white paper.

buffer amount, as applicable, and information necessary to calculate a firm's distribution limitations, including its capital conservation buffer, advanced approaches capital conservation buffer, leverage buffer, eligible retained income, and distributions. The proposal would have also added similar items to the applicable FR Y–14A schedule. This information would enable the Board and the public to identify any distribution limitations and monitor a bank holding company's performance on a quarterly basis and allow the Board to compare a firm's projected capital ratios to expected buffer requirements and implement the proposed evaluation of planned capital actions under the BHC baseline scenario.[51]

One commenter suggested that it was unnecessary to report eligible retained income, maximum payout ratio, maximum payout amount, and distributions and discretionary bonus payments unless the firm is subject to a maximum payout ratio.

The Board is adopting the proposed adjustments to the FR Y–9C, with some modifications to reflect changes made to the final rule. Firms will be required to report all items related to their buffer and potential limitations to provide critical information to the Board and public about the firm's capital adequacy and ability to continue to operate under stress. As the final rule does not include a stress leverage buffer requirement, the corresponding new line items on the FR Y–9C have been removed from the final FR Y–9C forms and instructions. Responses to these items will enable the Board and public to monitor a firm's capital adequacy relative to its requirements. The responses will also ensure that the Board and public can estimate the potential consequences for a firm if it were to undergo a period of stress.

The proposed changes to the FR Y–14A are also being adopted as proposed, with some modifications to reflect changes made to the final rule. Similar to the FR Y–9C, line items related to the stress leverage buffer requirement have not been added to the FR Y–14A in the final rule. In addition, the Board has not added items to the FR Y–14A related to buffer requirements that are reported on the FR Y–9C by firms not subject to the capital plan rule, as these items are not applicable to FR Y–14 reporters. The changes to the FR Y–14A reporting forms and instructions are essential to understand a firm's projected capital positions under stress and will help shape the Federal Reserve's evaluation of the firm's capital planning processes.

As described in Section IV above, the final rule provides that, within two business days of receipt of notice of its stress capital buffer requirement, a firm will be required to assess whether its planned capital distributions are consistent with the effective capital distribution limitations that will apply on a pro forma basis under the BHC baseline scenario throughout the fourth through seventh quarters of the planning horizon. In the event of an inconsistency, a firm will be required to reduce the capital distributions in its capital plan to be consistent with such limitations for those quarters of the planning horizon and provide the Board with its final planned capital actions following any such adjustments.[52]

To implement this requirement, a firm will be required to report its capital distributions on the FR Y–14A filed in connection with its initial capital plan on April 5, and in the event of any downward adjustments to its planned capital distributions, resubmit the FR Y–14A summary schedule within two business days of receiving its stress capital buffer requirement, that reflect the stress capital buffer requirement and its reduced planned capital distributions.[53] At the time a firm submits its capital plan and FR Y–14A report as of December 31, the firm will not be aware of its stress capital buffer requirement for the upcoming cycle. For simplicity, the instructions contemplate that the firm will report the stress capital buffer requirement currently in effect, and assume that the stress capital buffer requirement remain constant through the planning horizon. However, the capital plan rule requires the firm's planned capital distributions to be consistent with effective capital distribution limitations in the fourth through seventh quarters of the planning horizon and not the distribution limitations in effect in the prior cycle. Thus, it will be possible for a firm to include planned capital distributions in its FR Y–14A as of December 31 that will exceed those permitted under the previous cycle's capital plan, but be consistent with the capital plan rule because the firm's stress capital buffer requirement declined.

The Board is also making changes to its regulatory reports to reflect the changes to the circumstances in which a firm is required to seek prior approval from the Federal Reserve before making capital distributions in excess of these included in the firm's capital plan. Currently, a firm is required to submit an updated FR Y–14A Schedule C, Regulatory Capital Instruments prior to making any additional capital distributions. As discussed in Section IV.C, the Board is eliminating the prior approval requirement. To reflect these changes in the regulatory reports, a firm will be required to submit an updated FR Y–14A Schedule C, Regulatory Capital Instruments, within 15 days after notice of distributions in excess of planned distributions as required under the capital plan rule. This reporting requirement will allow the Board to continue to monitor a firm's capital distributions while reducing burden.

IX. Administrative Law Matters

A. Paperwork Reduction Act

Certain provisions of the final rule contain ''collections of information'' within the meaning of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The Board may not conduct or sponsor, and a respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. The Board reviewed the final rule under the authority delegated to the Board by OMB. The Board did not receive any specific comments on the PRA for the FR Y–14 or FR Y–13.

Regarding the proposed changes to the FR Y–9C, one commenter suggested that it was unnecessary for firms subject to the capital plan rule to report eligible retained income, maximum payout ratio, maximum payout amount, and distributions and discretionary bonus payments unless the firm is subject to a maximum payout ratio. As noted above, responses to these items will enable the Board and public to monitor a firm's capital adequacy relative to its requirements. The responses will also ensure that the Board and public can estimate the potential consequences for a firm if it were to undergo a period of stress.

The final rule contains reporting requirements subject to the PRA. As described further below, the Board is revising the reporting requirements

[51] A firm generally will only be required to report this information annually in connection with its capital plan submission.

[52] The final rule also permits a firm to reduce its planned capital distributions if the firm's planned capital distributions are consistent with effective capital distribution limitations.

[53] In the event that a firm requests reconsideration of its stress capital buffer requirement, a firm must evaluate its planned capital distributions in light of any modifications to its stress capital buffer requirement. The firm may be required to reduce or permitted to increase its capital distributions depending on any modifications, and must provide the Board with its final planned capital actions reflecting those adjustments. In the event of any adjustment, the firm will be required to file the FR Y–14A to reflect its revised planned capital distributions.

found in section 12 CFR 225.8. Additionally, the Board is revising certain other collections of information to reflect the changes proposed in the proposed rule.

Adopted Revision, With Extension for Three Years, of the Following Information Collections:

(1) *Report title:* Financial Statements for Holding Companies.

Agency form number: FR Y–9C; FR Y–9LP; FR Y–9SP; FR Y–9ES; FR Y–9CS.

OMB control number: 7100–0128.

Effective date: December 31, 2020.

Frequency: Quarterly, semiannually, and annually.

Affected public: Businesses or other for-profit.

Respondents: Bank holding companies (BHCs), savings and loan holding companies (SLHCs),[54] securities holding companies (SHCs), and U.S. intermediate holding companies (IHCs) (collectively, holding companies (HCs)).

Estimated number of respondents:

FR Y–9C (non AA HCs) with less than $5 billion in total assets—155,

FR Y–9C (non AA HCs) with $5 billion or more in total assets—189,

FR Y–9C (AA HCs)—19,

FR Y–9LP—434,

FR Y–9SP—3,960,

FR Y–9ES—83,

FR Y–9CS—236.

Estimated average hours per response:

Reporting

FR Y–9C (non AA HCs) with less than $5 billion in total assets—40.48,

FR Y–9C (non AA HCs) with $5 billion or more in total assets—46.45,

FR Y–9C (AA HCs)—48.59,

FR Y–9LP—5.27,

FR Y–9SP—5.40,

FR Y–9ES—0.50,

FR Y–9CS—0.50.

Recordkeeping

FR Y–9C (non AA HCs) with less than $5 billion in total assets—1,

FR Y–9C (non AA HCs) with $5 billion or more in total assets—1,

FR Y–9C (AA HCs)—1,

FR Y–9LP—1,

FR Y–9SP—0.50,

FR Y–9ES—0.50,

FR Y–9CS—0.50.

Estimated annual burden hours:

Reporting

FR Y–9C (non AA HCs) with less than $5 billion in total assets—25,098,

FR Y–9C (non AA HCs) with $5 billion or more in total assets—35,116,

FR Y–9C (AA HCs)—3,693,

FR Y–9LP—9,149,

FR Y–9SP—42,768,

FR Y–9ES—42,

FR Y–9CS—471.

Recordkeeping

FR Y–9C (non AA HCs) with less than $5 billion in total assets—620,

FR Y–9C (non AA HCs) with $5 billion or more in total assets—756,

FR Y–9C (AA HCs)—76,

FR Y–9LP—1,736,

FR Y–9SP—3,960,

FR Y–9ES—42,

FR Y–9CS—472.

General description of report: The FR Y–9 family of reporting forms continues to be the primary source of financial data on holding companies that examiners rely on in the intervals between on-site inspections. Financial data from these reporting forms are used to detect emerging financial problems, to review performance and conduct pre-inspection analysis, to monitor and evaluate capital adequacy, to evaluate holding company mergers and acquisitions, and to analyze a holding company's overall financial condition to ensure the safety and soundness of its operations. The FR Y–9C, FR Y–9LP, and FR Y–9SP serve as standardized financial statements for the consolidated holding company. The Board requires HCs to provide standardized financial statements to fulfill the Board's statutory obligation to supervise these organizations. The FR Y–9ES is a financial statement for HCs that are Employee Stock Ownership Plans. The Board uses the FR Y–9CS (a free-form supplement) to collect additional information deemed to be critical and needed in an expedited manner. HCs file the FR Y–9C on a quarterly basis, the FR Y–9LP quarterly, the FR Y–9SP semiannually, the FR Y–9ES annually, and the FR Y–9CS on a schedule that is determined when this supplement is used.

Legal authorization and confidentiality: The Board has the authority to impose the reporting and recordkeeping requirements associated with the FR Y–9 family of reports on BHCs pursuant to section 5 of the Bank Holding Company Act of 1956 (BHC Act) (12 U.S.C. 1844); on SLHCs pursuant to section 10(b)(2) and (3) of the Home Owners' Loan Act (12 U.S.C. 1467a(b)(2) and (3)), as amended by sections 369(8) and 604(h)(2) of the Dodd-Frank Wall Street and Consumer Protection Act (Dodd-Frank Act); on U.S. IHCs pursuant to section 5 of the BHC Act (12 U.S.C 1844), as well as pursuant to sections 102(a)(1) and 165 of the Dodd-Frank Act (12 U.S.C. 511(a)(1) and 5365); and on securities holding companies pursuant to section 618 of the Dodd-Frank Act (12 U.S.C. 1850a(c)(1)(A)). The obligation to submit the FR Y–9 series of reports, and the recordkeeping requirements set forth in the respective instructions to each report, are mandatory.

With respect to the FR Y–9C report, Schedule HI's data item 7(g) ''FDIC deposit insurance assessments,'' Schedule HC–P's data item 7(a) ''Representation and warranty reserves for 1–4 family residential mortgage loans sold to U.S. government agencies and government sponsored agencies,'' and Schedule HC–P's data item 7(b) ''Representation and warranty reserves for 1–4 family residential mortgage loans sold to other parties'' are considered confidential commercial and financial information. Such treatment is appropriate under exemption 4 of the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)(4)) because these data items reflect commercial and financial information that is both customarily and actually treated as private by the submitter, and which the Board has previously assured submitters will be treated as confidential. It also appears that disclosing these data items may reveal confidential examination and supervisory information, and in such instances, this information would also be withheld pursuant to exemption 8 of the FOIA (5 U.S.C. 552(b)(8)), which protects information related to the supervision or examination of a regulated financial institution.

In addition, for both the FR Y–9C report and the FR Y–9SP report, Schedule HC's memorandum item 2.b., the name and email address of the external auditing firm's engagement partner, is considered confidential commercial information and protected by exemption 4 of the FOIA (5 U.S.C. 552(b)(4)) if the identity of the engagement partner is treated as private information by HCs. The Board has assured respondents that this information will be treated as confidential since the collection of this data item was proposed in 2004.

Aside from the data items described above, the remaining data items on the FR Y–9C report and the FR Y–9SP report are generally not accorded confidential treatment. The data items collected on FR Y–9LP, FR Y–9ES, and FR Y–9CS reports, are also generally not accorded confidential treatment. As provided in the Board's Rules Regarding Availability of Information (12 CFR part 261), however, a respondent may request confidential treatment for any

[54] An SLHC must file one or more of the FR Y–9 family of reports unless it is: (1) A grandfathered unitary SLHC with primarily commercial assets and thrifts that make up less than 5 percent of its consolidated assets; or (2) a SLHC that primarily holds insurance-related assets and does not otherwise submit financial reports with the SEC pursuant to section 13 or 15(d) of the Securities Exchange Act of 1934.

data items the respondent believes should be withheld pursuant to a FOIA exemption. The Board will review any such request to determine if confidential treatment is appropriate, and will inform the respondent if the request for confidential treatment has been denied.

To the extent the instructions to the FR Y–9C, FR Y–9LP, FR Y–9SP, and FR Y–9ES reports each respectively direct the financial institution to retain the workpapers and related materials used in preparation of each report, such material would only be obtained by the Board as part of the examination or supervision of the financial institution. Accordingly, such information is considered confidential pursuant to exemption 8 of the FOIA (5 U.S.C. 552(b)(8)). In addition, the workpapers and related materials may also be protected by exemption 4 of the FOIA, to the extent such financial information is treated as confidential by the respondent (5 U.S.C. 552(b)(4)).

Current actions: The final rule will modify the FR Y–9C for holding companies subject to the capital plan rule in order to collect information regarding a firm's stress capital buffer requirement, GSIB surcharge, countercyclical capital buffer amount, as applicable, and any applicable distribution limitations under the regulatory capital rule. Specifically, the final rule will add new line items to the FR Y–9C Schedule HC–R Part I to collect the following information from holding companies subject to the capital plan rule: (1) The firm's capital conservation buffer requirements (including its standardized approach capital conservation buffer requirement and the advanced approaches capital conservation buffer requirement) and leverage buffer requirement; (2) the firm's capital conservation buffer, advanced approaches capital conservation buffer, and, as applicable, leverage buffer as of the preceding quarter-end, which is the difference between the firm's relevant capital ratio and the relevant minimum requirement; and (3) information needed to calculate the firm's maximum payout amount, including the firm's planned total capital distributions, eligible retained income, and maximum payout ratio. The new line items will apply to top-tier holding companies subject to the Board's capital plan rule (BHCs and IHCs with total consolidated assets of $100 billion or more), for a total of 39 of the existing FR Y–9C respondents. The Board estimates that revisions to the FR Y–9 would increase the estimated average hours per response for FR Y–9C (non AA HCs) with $5 billion or more in total assets filers by 0.11 hours and FR Y–9C (AA HCs) filers by 1 hour. The Board estimates that revisions to the FR Y–9 would increase the estimated annual burden by 159 hours. The draft reporting form and instructions for the FR Y–9C are available at *https://www.federalreserve.gov/apps/reportforms/review.aspx.*

(2) *Report title:* Capital Assessments and Stress Testing.

Agency form number: FR Y–14A/Q/M.

OMB control number: 7100–0341.

Effective date: The revisions are effective with the December 31, 2020, as-of date, except for the revisions to FR Y–14A, Schedule C, which are effective when the final rule goes into effect.

Frequency: Annually, quarterly, and monthly.

Affected public: Businesses or other for-profit.

Respondents: These collections of information are applicable to bank holding companies (BHCs), U.S. intermediate holding companies (IHCs), and savings and loan holding companies (SLHCs) [55] with $100 billion or more in total consolidated assets, as based on: (i) The average of the firm's total consolidated assets in the four most recent quarters as reported quarterly on the firm's Consolidated Financial Statements for Holding Companies (FR Y–9C); or (ii) if the firm has not filed an FR Y–9C for each of the most recent four quarters, then the average of the firm's total consolidated assets in the most recent consecutive quarters as reported quarterly on the firm's FR Y–9Cs. Reporting is required as of the first day of the quarter immediately following the quarter in which the respondent meets this asset threshold, unless otherwise directed by the Board.

Estimated number of respondents: FR Y–14A/Q—36; FR Y–14M—34.[56]

Estimated average hours per response:

FR Y–14A—1,085,

FR Y–14Q—1,920,

FR Y–14M—1,072,

FR Y–14 Ongoing Automation Revisions—480,

FR Y–14 Attestation—2,560.

Estimated annual burden hours:

FR Y–14A—39,060,

FR Y–14Q—276,480,

FR Y–14M—437,376,

FR Y–14 Ongoing Automation Revisions—17,280,

FR Y–14 Attestation—33,280.

General description of report: This family of information collections is composed of the following three reports:

The FR Y–14A collects quantitative projections of balance sheet, income, losses, and capital across a range of macroeconomic scenarios and qualitative information on methodologies used to develop internal projections of capital across scenarios.[57]

The quarterly FR Y–14Q collects granular data on various asset classes, including loans, securities, trading assets, and PPNR for the reporting period.

The monthly FR Y–14M is comprised of three retail portfolio- and loan-level schedules, and one detailed address-matching schedule to supplement two of the portfolio and loan-level schedules.

The data collected through the FR Y–14A/Q/M reports provide the Board with the information needed to help ensure that large firms have strong, firm-wide risk measurement and management processes supporting their internal assessments of capital adequacy and that their capital resources are sufficient given their business focus, activities, and resulting risk exposures. The FR Y–14 reports are used to support the Board's annual Comprehensive Capital Analysis and Review (CCAR) and Dodd-Frank Act Stress Test (DFAST) exercises, which complement other Board supervisory efforts aimed at enhancing the continued viability of large firms, including continuous monitoring of firms' planning and management of liquidity and funding resources, as well as regular assessments of credit, market and operational risks, and associated risk management practices. Information gathered in this data collection is also used in the supervision and regulation of respondent financial institutions.

[55] SLHCs with $100 billion or more in total consolidated assets become members of the FR Y–14Q and FR Y–14M panels effective June 30, 2020, and the FR Y–14A panel effective December 31, 2020. *See* 84 FR 59032 (November 1, 2019).

[56] The estimated number of respondents for the FR Y–14M is lower than for the FR Y–14Q and FR Y–14A because, in recent years, certain respondents to the FR Y–14A and FR Y–14Q have not met the materiality thresholds to report the FR Y–14M due to their lack of mortgage and credit activities. The Board expects this situation to continue for the foreseeable future.

[57] On October 10, 2019, the Board issued a final rule that eliminated the requirement for firms subject to Category IV standards to conduct and publicly disclose the results of a company-run stress test. *See* 84 FR 59032 (Nov. 1, 2019). That final rule maintained the existing FR Y–14 substantive reporting requirements for these firms in order to provide the Board with the data it needs to conduct supervisory stress testing and inform the Board's ongoing monitoring and supervision of its supervised firms. However, as noted in the final rule, the Board intends to provide greater flexibility to banking organizations subject to Category IV standards in developing their annual capital plans and consider further change to the FR Y–14 forms as part of a separate proposal. *See* 84 FR 59032, 59063.

Respondent firms are currently required to complete and submit up to 17 filings each year: One annual FR Y–14A filing, four quarterly FR Y–14Q filings, and 12 monthly FR Y–14M filings. Compliance with the information collection is mandatory.

Legal authorization and confidentiality: The Board has the authority to require BHCs file the FR Y–14 reports pursuant to section 5(c) of the BHC Act (12 U.S.C. 1844(c)), and pursuant to section 165(i) of the Dodd-Frank Act (12 U.S.C. 5365(i)), as amended by section 401(a) and (e) of the Economic Growth, Regulatory Relief, and Consumer Protection Act (EGRRCPA).[58] The Board has authority to require SLHCs file the FR Y–14 reports pursuant to section 10(b) of the Home Owners' Loan Act (12 U.S.C. 1467a(b)), as amended by section 369(8) and 604(h)(2) of the Dodd-Frank Act. Lastly, the Board has authority to require IHCs file the FR Y–14 reports pursuant to section 5 of the BHC Act (12 U.S.C 1844), as well as pursuant to sections 102(a)(1) and 165 of the Dodd-Frank Act (12 U.S.C. 5311(a)(1) and 5365).[59] In addition, section 401(g) of EGRRCPA (12 U.S.C. 5365) note, provides that the Board has the authority to establish enhanced prudential standards for foreign banking organizations with total consolidated assets of $100 billion or more, and clarifies that nothing in section 401 ''shall be construed to affect the legal effect of the final rule of the Board . . . entitled 'Enhanced Prudential Standard for [BHCs] and Foreign Banking Organizations' (79 FR 17240 (March 27, 2014)), as applied to foreign banking organizations with total consolidated assets equal to or greater than $100 million.''[60] The information reported in the FR Y–14 reports is collected as part of the Board's supervisory process, and therefore, such information is afforded confidential treatment pursuant to exemption 8 of the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)(8)). In addition, confidential commercial or financial information, which a submitter actually and customarily treats as private, and which has been provided pursuant to an express assurance of confidentiality by the Board, is considered exempt from disclosure under exemption 4 of the FOIA (5 U.S.C. 552(b)(4).

Current actions: To implement the reporting requirements of the final rule, the Board revised the FR Y–14A report to in order to collect information regarding a firm's capital conservation buffer requirements (including the stress capital buffer requirement) and any applicable distribution limitations under the regulatory capital rule. Specifically, the Board revised the FR Y–14A, Schedule A.1.d (Capital) report to collect the following items under firm baseline conditions: (1) The firm's capital conservation buffer requirement and, as applicable, leverage buffer requirement for each quarter of the planning horizon; (2) the firm's capital conservation buffer and, as applicable, leverage buffer as of the preceding quarter-end for each quarter of the planning horizon, which is the difference between the firm's relevant capital ratio and the relevant minimum requirement; and (3) information needed to calculate the firm's maximum payout amount, including the firm's planned total capital distributions, eligible retained income, and maximum payout ratio for each quarter of the planning horizon. Finally, to align with the final rule, the Board has revised the FR Y–14A instructions to require a firm to submit an updated FR Y–14A, Schedule C (Regulatory Capital Instruments), within 15 days after notice of distributions in excess of planned distributions as required under the capital plan rule. The Board estimates that revisions to the FR Y–14 would increase the estimated average hours per response for FR Y–14A filers by 20 hours. The Board estimates that revisions to the FR Y–14 would increase the estimated annual burden by 720 hours. The draft reporting form and instructions for the FR Y–14A are available at *https://www.federalreserve.gov/apps/reportforms/review.aspx.*

(3) *Title of information collection:* Reporting and Recordkeeping Requirements Associated with Regulation Y (Capital Plans).

Agency form number: FR Y–13.

OMB control number: 7100–0342.

Effective date: Effective date of the final rule.

Frequency: Annually.

Affected public: Businesses or other for-profit.

Respondents: BHCs and IHCs.

Estimated number of respondents:

Reporting

Section 225.8(e)(1)(ii)—34.
Section 225.8(e)(3)—25.
Section 225.8(e)(4)—10.
Section 225.8(h)(2)(ii)(B)—2.
Section 225.8(j)—2.
Sections 225.8(k)(1) and (2)—3.
Section 225.8(k)(4)—2.

Recordkeeping

Section 225.8(e)(1)(i)—34.
Section 225.8(e)(1)(iii)—34.

Estimated average hours per response:

Reporting[61]

Section 225.8(e)(1)(ii)—80.
Section 225.8(e)(3)—1,005.
Section 225.8(e)(4)—100.
Section 225.8(h)(2)(ii)(B)—2.
Section 225.8(j)—16.
Sections 225.8(k)(1) and (2)—100.
Section 225.8(k)(4)—16.

Recordkeeping

Section 225.8(e)(1)(i)—8,920.
Section 225.8(e)(1)(iii)—100.

Estimated annual burden hours:

Reporting

Section 225.8(e)(1)(ii)—2,720.
Section 225.8(e)(3)—25,125.
Section 225.8(e)(4)—1,000.
Section 225.8(h)(2)(ii)(B)—4.
Section 225.8(j)—32.
Sections 225.8(k)(1) and (2)—300.
Section 225.8(k)(4)—32.

Recordkeeping

Section 225.8(e)(1)(i)—303,280.
Section 225.8(e)(1)(iii)—3,400.

General description of report: Regulation Y (12 CFR part 225) requires large bank holding companies (BHCs) and U.S. intermediate holding companies (IHCs) to submit capital plans to the Federal Reserve on an annual basis and to request prior approval from the Federal Reserve under certain circumstances before making a capital distribution.

Legal authorization and confidentiality: Section 616(a) of the

[58] Public Law 115–174, Title IV § 401(a) and (e), 132 Stat. 1296, 1356–59 (2018).

[59] Section 165(b)(2) of the Dodd-Frank Act, 12 U.S.C. 5365(b)(2), refers to ''foreign-based bank holding company.'' Section 102(a)(1) of the Dodd-Frank Act, 12 U.S.C. 5311(a)(1), defines ''bank holding company'' for purposes of Title I of the Dodd-Frank Act to include foreign banking organizations that are treated as bank holding companies under section 8(a) of the International Banking Act of 1978, 12 U.S.C. 3106(a). The Board has required, pursuant to section 165(b)(1)(B)(iv) of the Dodd-Frank Act, 12 U.S.C. 5365(b)(1)(B)(iv), certain foreign banking organizations subject to section 165 of the Dodd-Frank Act to form U.S. intermediate holding companies. Accordingly, the parent foreign-based organization of a U.S. IHC is treated as a BHC for purposes of the BHC Act and section 165 of the Dodd-Frank Act. Because Section 5(c) of the BHC Act authorizes the Board to require reports from subsidiaries of BHCs, section 5(c) provides additional authority to require U.S. IHCs to report the information contained in the FR Y–14 reports.

[60] The Board's Final Rule referenced in section 401(g) of EGRRCPA specifically stated that the Board would require IHCs to file the FR Y–14 reports. *See* 79 FR 17240, 17304 (March 27, 2014).

[61] The reporting requirement in section 225.8(l) is identical to a reporting requirement in the FR Y–14A. The burden associated with this requirement is accounted for in the burden estimate for the FR Y–14 information collection.

Dodd-Frank Act amended section 5(b) of the Bank Holding Company Act of 1956 (BHC Act) (12 U.S.C. 1844(b)) to specifically authorize the Board to issue regulations and orders relating to capital requirements for BHCs. The Board is also authorized to collect and require reports from BHCs pursuant to section 5(c) of the BHC Act (12 U.S.C. 1844(c)). Additionally, the Board's rulemaking authority for the information collection and disclosure requirements associated with the FR Y–13 is found in sections 908 and 910 of the International Lending Supervision Act of 1983, as amended (12 U.S.C. 3907 and 3909). Additional support for FR Y–13 is found in sections 165 and 166 of the Dodd-Frank Act (12 U.S.C. 5365 and 5366).[62] The obligation to respond to this information collection is mandatory.

The capital plan information submitted by the covered BHC will consist of confidential and proprietary modeling information and highly sensitive business plans, such as acquisition plans submitted to the Board for approval. Therefore, it appears the information will be subject to withholding under exemption 4 of the Freedom of Information Act (5 U.S.C. 552(b)(4)).

Current actions: The final rule modifies the process by which a firm determines the final planned capital distributions included in its capital plan. In addition, under certain conditions, the final rule removes the requirement for a firm to request prior approval to make distributions that exceed the amount included in its capital plan. The final rule also modifies the timeline and procedures related to a firm's stress capital buffer requirement, requests for reconsideration, and capital plan resubmissions. The Board estimates that response to notice; adjustments to planned capital distributions (reporting) (225.8(h)(2)(ii)) would be 2 hours per response. The Board estimates that revisions to the FR Y–13 would decrease the estimated annual burden by 2,028 hours.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires that, in connection with a final rulemaking, an agency prepare and make available for public comment a final regulatory flexibility analysis describing the impact of the proposed rule on small entities.[63] However, a final regulatory flexibility analysis is not required if the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. The Small Business Administration (SBA) has defined ''small entities'' to include banking organizations with total assets of less than or equal to $600 million that are independently owned and operated or owned by a holding company with less than or equal to $600 million in total assets.[64] For the reasons described below and under section 605(b) of the RFA, the Board certifies that the final rule will not have a significant economic impact on a substantial number of small entities. As of December 31, 2019, there were 2,799 bank holding companies, 171 savings and loan holding companies, and 497 state member banks that would fit the SBA's current definition of ''small entity'' for purposes of the RFA.

In connection with the proposed rule, the Board stated that it did not believe the proposed rule would have a significant economic impact on a substantial number of small entities. Nevertheless, the Board published and invited comment on an initial regulatory flexibility analysis of the proposed rule. No comments were received on the initial regulatory flexibility analysis.

The Board is finalizing amendments to Regulations Q,[65] Y,[66] and YY[67] that would affect the regulatory requirements that apply to bank holding companies with total consolidated assets of $50 billion or more, any nonbank financial company supervised by the Board that becomes subject to the capital planning requirements pursuant to a rule or order of the Board, and to U.S. intermediate holding companies established pursuant to Regulation YY. The reasons and justification for the final rule are described above in more detail in this **SUPPLEMENTARY INFORMATION**.

The Board has considered whether to conduct a final regulatory flexibility analysis in connection with this final rule. However, the assets of institutions subject to this final rule substantially exceed the $600 million asset threshold under which a banking organization is considered a ''small entity'' under SBA regulations. Because the final rule is not likely to apply to any depository institution or company with assets of $600 million or less, it is not expected to apply to any small entity for purposes of the RFA. The Board does not believe that the final rule duplicates, overlaps, or conflicts with any other Federal rules. In light of the foregoing, the Board certifies that the final rule will not have a significant economic impact on a substantial number of small entities supervised.

C. Use of Plain Language

Section 722 of the Gramm-Leach-Bliley Act (Pub. L. 106–102, 113 Stat. 1338, 1471, 12 U.S.C. 4809) requires the federal banking agencies to use plain language in all proposed and final rules published after January 1, 2000. The Board has sought to present the proposed rule in a simple and straightforward manner, and invites comment on the use of plain language.

For example:

- Have we organized the material to suit your needs? If not, how could the rule be more clearly stated?
- Are the requirements in the rule clearly stated? If not, how could the rule be more clearly stated?
- Do the regulations contain technical language or jargon that is not clear? If so, which language requires clarification?
- Will a different format (grouping and order of sections, use of headings, paragraphing) make the regulation easier to understand? If so, what changes will make the regulation easier to understand?
- Will more, but shorter, sections be better? If so, which sections should be changed?
- What else could we do to make the regulation easier to understand?

List of Subjects

12 CFR Part 217

Administrative practice and procedure, Banks, Banking, Federal Reserve System, Holding companies, Reporting and recordkeeping requirements, Risk, Securities.

12 CFR Part 225

Administrative practice and procedure, Banks, Banking, Capital planning, Holding companies, Reporting

[62] Section 165 requires the Board to impose enhances prudential standards on large BHCs, including stress testing requirements; enhanced capital, liquidity, and risk management requirements; and a requirement to establish a risk committee. Section 166 requires the Board to impose early remediation requirements on large BHCs under which a large BHC experiencing financial distress must take specific remedial actions in order to minimize the probability that the company will become insolvent and to minimize the potential harm of such insolvency the United States.

[63] 5 U.S.C. 601 *et. seq.*

[64] *See* 13 CFR 121.201. Effective August 19, 2019, the Small Business Administration revised the size standards for banking organizations to $600 million in assets from $550 million in assets. *See* 84 FR 34261 (July 18, 2019). Consistent with the General Principles of Affiliation in 13 CFR 121.103, the Board counts the assets of all domestic and foreign affiliates when determining if the Board should classify a Board-supervised institution as a small entity.

[65] See 12 CFR part 217.

[66] See 12 CFR part 225.

[67] See 12 CFR part 252.

and recordkeeping requirements, Securities, Stress testing.

12 CFR Part 252

Administrative practice and procedure, Banks, banking, Credit, Federal Reserve System, Holding companies, Investments, Qualified financial contracts, Reporting and recordkeeping requirements, Securities.

Authority and Issuance

For the reasons stated in the Supplementary Information, the Board of Governors of the Federal Reserve System amends 12 CFR chapter II as follows:

PART 217—CAPITAL ADEQUACY OF BANK HOLDING COMPANIES, SAVINGS AND LOAN HOLDING COMPANIES, AND STATE MEMBER BANKS (REGULATION Q)

■ 1. The authority citation for part 217 continues to read as follows:

Authority: 12 U.S.C. 248(a), 321–338a, 481–486, 1462a, 1467a, 1818, 1828, 1831n, 1831o, 1831p-1, 1831w, 1835, 1844(b), 1851, 3904, 3906–3909, 4808, 5365, 5368, 5371.

■ 2. Section 217.11 is revised to read as follows:

§ 217.11 Capital conservation buffer, countercyclical capital buffer amount, and GSIB surcharge.

(a) *Capital conservation buffer*—(1) *Composition of the capital conservation buffer.* The capital conservation buffer is composed solely of common equity tier 1 capital.

(2) *Definitions.* For purposes of this section, the following definitions apply:

(i) *Eligible retained income.* (A) The eligible retained income of a Board-regulated institution is the Board-regulated institution's net income, calculated in accordance with the instructions to the Call Report or the FR Y–9C, as applicable, for the four calendar quarters preceding the current calendar quarter, net of any distributions and associated tax effects not already reflected in net income.

(B) Notwithstanding paragraph (a)(2)(i)(A) of this section, the eligible retained income of a Board-regulation institution subject to 12 CFR 225.8 is the average of the Board-regulated institution's net income, calculated in accordance with the instructions to the FR Y–9C for the four calendar quarters preceding the current calendar quarter, if:

(*1*) The Board-regulated institution is subject to a maximum payout ratio determined by its standardized approach capital conservation buffer under paragraph (c)(1)(ii) of this section; and

(*2*) The Board-regulated institution's standardized approach capital conservation buffer is greater than the sum of:

(*i*) 2.5 percent;

(*ii*) Any applicable countercyclical capital buffer amount calculated in accordance with paragraph (b) of this section; and

(*iii*) Any applicable GSIB surcharge calculated in accordance with paragraph (d) of this section.

(ii) *Maximum payout amount.* A Board-regulated institution's maximum payout amount for the current calendar quarter is equal to the Board-regulated institution's eligible retained income, multiplied by its maximum payout ratio.

(iii) *Maximum payout ratio.* The maximum payout ratio is the percentage of eligible retained income that a Board-regulated institution can pay out in the form of distributions and discretionary bonus payments during the current calendar quarter. For a Board-regulated institution that is not subject to 12 CFR 225.8, the maximum payout ratio is determined by the Board-regulated institution's capital conservation buffer, calculated as of the last day of the previous calendar quarter, as set forth in Table 1 to § 217.11(a)(4)(iv). For a Board-regulated institution that is subject to 12 CFR 225.8, the maximum payout ratio is determined under paragraph (c)(1)(ii) of this section.

(iv) *Private sector credit exposure.* Private sector credit exposure means an exposure to a company or an individual that is not an exposure to a sovereign, the Bank for International Settlements, the European Central Bank, the European Commission, the European Stability Mechanism, the European Financial Stability Facility, the International Monetary Fund, a MDB, a PSE, or a GSE.

(v) *Leverage buffer requirement.* A bank holding company's leverage buffer requirement is 2.0 percent.

(vi) *Stress capital buffer requirement.* A bank holding company's stress capital buffer requirement is the stress capital buffer requirement determined under 12 CFR 225.8.

(3) *Calculation of capital conservation buffer.* (i) A Board-regulated institution that is not subject to 12 CFR 225.8 has a capital conservation buffer equal to the lowest of the following ratios, calculated as of the last day of the previous calendar quarter:

(A) The Board-regulated institution's common equity tier 1 capital ratio minus the Board-regulated institution's minimum common equity tier 1 capital ratio requirement under § 217.10;

(B) The Board-regulated institution's tier 1 capital ratio minus the Board-regulated institution's minimum tier 1 capital ratio requirement under § 217.10; and

(C) The Board-regulated institution's total capital ratio minus the Board-regulated institution's minimum total capital ratio requirement under § 217.10; or

(ii) Notwithstanding paragraphs (a)(3)(i)(A) through (C) of this section, if a Board-regulated institution's common equity tier 1, tier 1 or total capital ratio is less than or equal to the Board-regulated institution's minimum common equity tier 1, tier 1 or total capital ratio requirement under § 217.10, respectively, the Board-regulated institution's capital conservation buffer is zero.

(4) *Limits on distributions and discretionary bonus payments.* (i) A Board-regulated institution that is not subject 12 CFR 225.8 shall not make distributions or discretionary bonus payments or create an obligation to make such distributions or payments during the current calendar quarter that, in the aggregate, exceed its maximum payout amount.

(ii) A Board-regulated institution that is not subject 12 CFR 225.8 and that has a capital conservation buffer that is greater than 2.5 percent plus 100 percent of its applicable countercyclical capital buffer amount in accordance with paragraph (b) of this section is not subject to a maximum payout amount under paragraph (a)(2)(ii) of this section.

(iii) Except as provided in paragraph (a)(4)(iv) of this section, a Board-regulated institution that is not subject to 12 CFR 225.8 may not make distributions or discretionary bonus payments during the current calendar quarter if the Board-regulated institution's:

(A) Eligible retained income is negative; and

(B) Capital conservation buffer was less than 2.5 percent as of the end of the previous calendar quarter.

(iv) *Prior approval.* Notwithstanding the limitations in paragraphs (a)(4)(i) through (iii) of this section, the Board may permit a Board-regulated institution that is not subject to 12 CFR 225.8 to make a distribution or discretionary bonus payment upon a request of the Board-regulated institution, if the Board determines that the distribution or discretionary bonus payment would not be contrary to the purposes of this section, or to the safety and soundness of the Board-regulated institution. In making such a determination, the Board will consider the nature and extent of the request and

the particular circumstances giving rise to the request.

TABLE 1 TO § 217.11(A)(4)(IV)—CALCULATION OF MAXIMUM PAYOUT AMOUNT

Capital conservation buffer	Maximum payout ratio
Greater than 2.5 percent plus 100 percent of the Board-regulated institution's applicable countercyclical capital buffer amount.	No payout ratio limitation applies.
Less than or equal to 2.5 percent plus 100 percent of the Board-regulated institution's applicable countercyclical capital buffer amount, *and* greater than 1.875 percent plus 75 percent of the Board-regulated institution's applicable countercyclical capital buffer amount.	60 percent.
Less than or equal to 1.875 percent plus 75 percent of the Board-regulated institution's applicable countercyclical capital buffer amount, *and* greater than 1.25 percent plus 50 percent of the Board-regulated institution's applicable countercyclical capital buffer amount.	40 percent.
Less than or equal to 1.25 percent plus 50 percent of the Board-regulated institution's applicable countercyclical capital buffer amount *and* greater than 0.625 percent plus 25 percent of the Board-regulated institution's applicable countercyclical capital buffer amount.	20 percent.
Less than or equal to 0.625 percent plus 25 percent of the Board-regulated institution's applicable countercyclical capital buffer amount.	0 percent.

(v) *Other limitations on distributions.* Additional limitations on distributions may apply under 12 CFR 225.4 and 12 CFR 263.202 to a Board-regulated institution that is not subject to 12 CFR 225.8.

(b) *Countercyclical capital buffer amount*—(1) *General.* An advanced approaches Board-regulated institution or a Category III Board-regulated institution must calculate a countercyclical capital buffer amount in accordance with this paragraph (b) for purposes of determining its maximum payout ratio under Table 1 to § 217.11(a)(4)(iv) and, if applicable, Table 2 to § 217.11(c)(4)(iii).

(i) *Extension of capital conservation buffer.* The countercyclical capital buffer amount is an extension of the capital conservation buffer as described in paragraph (a) or (c) of this section, as applicable.

(ii) *Amount.* An advanced approaches Board-regulated institution or a Category III Board-regulated institution has a countercyclical capital buffer amount determined by calculating the weighted average of the countercyclical capital buffer amounts established for the national jurisdictions where the Board-regulated institution's private sector credit exposures are located, as specified in paragraphs (b)(2) and (3) of this section.

(iii) *Weighting.* The weight assigned to a jurisdiction's countercyclical capital buffer amount is calculated by dividing the total risk-weighted assets for the Board-regulated institution's private sector credit exposures located in the jurisdiction by the total risk-weighted assets for all of the Board-regulated institution's private sector credit exposures. The methodology a Board-regulated institution uses for determining risk-weighted assets for purposes of this paragraph (b) must be the methodology that determines its risk-based capital ratios under § 217.10. Notwithstanding the previous sentence, the risk-weighted asset amount for a private sector credit exposure that is a covered position under subpart F of this part is its specific risk add-on as determined under § 217.210 multiplied by 12.5.

(iv) *Location.* (A) Except as provided in paragraphs (b)(1)(iv)(B) and (C) of this section, the location of a private sector credit exposure is the national jurisdiction where the borrower is located (that is, where it is incorporated, chartered, or similarly established or, if the borrower is an individual, where the borrower resides).

(B) If, in accordance with subpart D or E of this part, the Board-regulated institution has assigned to a private sector credit exposure a risk weight associated with a protection provider on a guarantee or credit derivative, the location of the exposure is the national jurisdiction where the protection provider is located.

(C) The location of a securitization exposure is the location of the underlying exposures, or, if the underlying exposures are located in more than one national jurisdiction, the national jurisdiction where the underlying exposures with the largest aggregate unpaid principal balance are located. For purposes of this paragraph (b), the location of an underlying exposure shall be the location of the borrower, determined consistent with paragraph (b)(1)(iv)(A) of this section.

(2) *Countercyclical capital buffer amount for credit exposures in the United States*—(i) *Initial countercyclical capital buffer amount with respect to credit exposures in the United States.* The initial countercyclical capital buffer amount in the United States is zero.

(ii) *Adjustment of the countercyclical capital buffer amount.* The Board will adjust the countercyclical capital buffer amount for credit exposures in the United States in accordance with applicable law.[1]

(iii) *Range of countercyclical capital buffer amount.* The Board will adjust the countercyclical capital buffer amount for credit exposures in the United States between zero percent and 2.5 percent of risk-weighted assets.

(iv) *Adjustment determination.* The Board will base its decision to adjust the countercyclical capital buffer amount under this section on a range of macroeconomic, financial, and supervisory information indicating an increase in systemic risk including, but not limited to, the ratio of credit to gross domestic product, a variety of asset prices, other factors indicative of relative credit and liquidity expansion or contraction, funding spreads, credit condition surveys, indices based on credit default swap spreads, options implied volatility, and measures of systemic risk.

(v) *Effective date of adjusted countercyclical capital buffer amount*—(A) *Increase adjustment.* A determination by the Board under paragraph (b)(2)(ii) of this section to increase the countercyclical capital buffer amount will be effective 12 months from the date of announcement, unless the Board establishes an earlier effective date and includes a statement articulating the reasons for the earlier effective date.

(B) *Decrease adjustment.* A determination by the Board to decrease the established countercyclical capital buffer amount under paragraph (b)(2)(ii)

[1] The Board expects that any adjustment will be based on a determination made jointly by the Board, OCC, and FDIC.

of this section will be effective on the day following announcement of the final determination or the earliest date permissible under applicable law or regulation, whichever is later.

(vi) *Twelve month sunset.* The countercyclical capital buffer amount will return to zero percent 12 months after the effective date that the adjusted countercyclical capital buffer amount is announced, unless the Board announces a decision to maintain the adjusted countercyclical capital buffer amount or adjust it again before the expiration of the 12-month period.

(3) *Countercyclical capital buffer amount for foreign jurisdictions.* The Board will adjust the countercyclical capital buffer amount for private sector credit exposures to reflect decisions made by foreign jurisdictions consistent with due process requirements described in paragraph (b)(2) of this section.

(c) *Calculation of buffers for Board-regulated institutions subject to 12 CFR 225.8*— (1) *Limits on distributions and discretionary bonus payments.* (i) A Board-regulated institution that is subject to 12 CFR 225.8 shall not make distributions or discretionary bonus payments or create an obligation to make such distributions or payments during the current calendar quarter that, in the aggregate, exceed its maximum payout amount.

(ii) *Maximum payout ratio.* The maximum payout ratio of a Board-regulated institution that is subject to 12 CFR 225.8 is the lowest of the payout ratios determined by its standardized approach capital conservation buffer; if applicable, advanced approaches capital conservation buffer; and, if applicable, leverage buffer; as set forth in Table 2 to § 217.11(c)(4)(iii).

(iii) *Capital conservation buffer requirements.* A Board-regulated institution that is subject to 12 CFR 225.8 has:

(A) A standardized approach capital conservation buffer requirement equal to its stress capital buffer requirement plus its applicable countercyclical capital buffer amount in accordance with paragraph (b) of this section plus its applicable GSIB surcharge in accordance with paragraph (d) of this section; and

(B) If the Board-regulated institution calculates risk-weighted assets under subpart E of this part, an advanced approaches capital conservation buffer requirement equal to 2.5 percent plus the Board-regulated institution's countercyclical capital buffer amount in accordance with paragraph (b) of this section plus its applicable GSIB surcharge in accordance with paragraph (d) of this section.

(iv) *No maximum payout amount limitation.* A Board-regulated institution that is subject to 12 CFR 225.8 is not subject to a maximum payout amount under paragraph (a)(2)(ii) of this section if it has:

(A) A standardized approach capital conservation buffer, calculated under paragraph (c)(2) of this section, that is greater than its standardized approach capital conservation buffer requirement calculated under paragraph (c)(1)(iii)(A) of this section;

(B) If applicable, an advanced approaches capital conservation buffer, calculated under paragraph (c)(3) of this section, that is greater than the Board-regulated institution's advanced approaches capital conservation buffer requirement calculated under paragraph (c)(1)(iii)(B) of this section; and

(C) If applicable, a leverage buffer, calculated under paragraph (c)(4) of this section, that is greater than its leverage buffer requirement as calculated under paragraph (a)(2)(v) of this section.

(v) *Negative eligible retained income.* Except as provided in paragraph (c)(1)(vi) of this section, a Board-regulated institution that is subject to 12 CFR 225.8 may not make distributions or discretionary bonus payments during the current calendar quarter if, as of the end of the previous calendar quarter, the Board-regulated institution's:

(A) Eligible retained income is negative; and

(B)(*1*) Standardized approach capital conservation buffer was less than its stress capital buffer requirement; or

(*2*) If applicable, advanced approaches capital conservation buffer was less than 2.5 percent; or

(*3*) If applicable, leverage buffer was less than its leverage buffer requirement.

(vi) *Prior approval.* Notwithstanding the limitations in paragraphs (c)(1)(i) through (v) of this section, the Board may permit a Board-regulated institution that is subject to 12 CFR 225.8 to make a distribution or discretionary bonus payment upon a request of the Board-regulated institution, if the Board determines that the distribution or discretionary bonus payment would not be contrary to the purposes of this section, or to the safety and soundness of the Board-regulated institution. In making such a determination, the Board will consider the nature and extent of the request and the particular circumstances giving rise to the request.

(v) *Other limitations on distributions.* Additional limitations on distributions may apply under 12 CFR 225.4, 12 CFR 225.8, 12 CFR 252.63, 12 CFR 252.165, and 12 CFR 263.202 to a Board-regulated institution that is subject to 12 CFR 225.8.

(2) *Standardized approach capital conservation buffer.* (i) The standardized approach capital conservation buffer for Board-regulated institutions subject to 12 CFR 225.8 is composed solely of common equity tier 1 capital.

(ii) A Board-regulated institution that is subject to 12 CFR 225.8 has a standardized approach capital conservation buffer that is equal to the lowest of the following ratios, calculated as of the last day of the previous calendar quarter:

(A) The ratio calculated by the Board-regulated institution under § 217.10(b)(1) or (c)(1)(i), as applicable, minus the Board-regulated institution's minimum common equity tier 1 capital ratio requirement under § 217.10(a);

(B) The ratio calculated by the Board-regulated institution under § 217.10(b)(2) or (c)(2)(i), as applicable, minus the Board-regulated institution's minimum tier 1 capital ratio requirement under § 217.10(a); and

(C) The ratio calculated by the Board-regulated institution under § 217.10(b)(3) or (c)(3)(i), as applicable, minus the Board-regulated institution's minimum total capital ratio requirement under § 217.10(a).

(iii) Notwithstanding paragraph (c)(2)(ii) of this section, if any of the ratios calculated by the Board-regulated institution under § 217.10(b)(1), (2), or (3), or if applicable § 217.10(c)(1)(i), (c)(2)(i), or (c)(3)(i) is less than or equal to the Board-regulated institution's minimum common equity tier 1 capital ratio, tier 1 capital ratio, or total capital ratio requirement under § 217.10(a), respectively, the Board-regulated institution's capital conservation buffer is zero.

(3) *Advanced approaches capital conservation buffer.* (i) The advanced approaches capital conservation buffer is composed solely of common equity tier 1 capital.

(ii) A Board-regulated institution that calculates risk-weighted assets under subpart E has an advanced approaches capital conservation buffer that is equal to the lowest of the following ratios, calculated as of the last day of the previous calendar quarter:

(A) The ratio calculated by the Board-regulated institution under § 217.10(c)(1)(ii) minus the Board-regulated institution's minimum common equity tier 1 capital ratio requirement under § 217.10(a);

(B) The ratio calculated by the Board-regulated institution under § 217.10(c)(2)(ii) minus the Board-

regulated institution's minimum tier 1 capital ratio requirement under § 217.10(a); and

(C) The ratio calculated by the Board-regulated institution under § 217.10(c)(3)(ii) minus the Board-regulated institution's minimum total capital ratio requirement under § 217.10(a).

(iii) Notwithstanding paragraph (c)(3)(ii) of this section, if any of the ratios calculated by the Board-regulated institution under § 217.10(c)(1)(ii), (c)(2)(ii), or (c)(3)(ii) is less than or equal to the Board-regulated institution's minimum common equity tier 1 capital ratio, tier 1 capital ratio, or total capital ratio requirement under § 217.10(a), respectively, the Board-regulated institution's advanced approaches capital conservation buffer is zero.

(4) *Leverage buffer.* (i) The leverage buffer is composed solely of tier 1 capital.

(ii) A global systemically important BHC has a leverage buffer that is equal to the global systemically important BHC's supplementary leverage ratio minus 3 percent, calculated as of the last day of the previous calendar quarter.

(iii) Notwithstanding paragraph (c)(4)(ii) of this section, if the global systemically important BHC's supplementary leverage ratio is less than or equal to 3 percent, the global systemically important BHC's leverage buffer is zero.

TABLE 2 TO § 217.11(c)(4)(iii)—CALCULATION OF MAXIMUM PAYOUT RATIO

Capital buffer [1]	Payout ratio
Greater than the Board-regulated institution's buffer requirement [2]	No payout ratio limitation applies.
Less than or equal to 100 percent of the Board-regulated institution's buffer requirement, *and* greater than 75 percent of the Board-regulated institution's buffer requirement.	60 percent.
Less than or equal to 75 percent of the Board-regulated institution's buffer requirement, *and* greater than 50 percent of the bank holding company's buffer requirement.	40 percent.
Less than or equal to 50 percent of the Board-regulated institution's buffer requirement, *and* greater than 25 percent of the Board-regulated institution's buffer requirement.	20 percent.
Less than or equal to 25 percent of the Board-regulated institution's buffer requirement	0 percent.

[1] A Board-regulated institution's "capital buffer" means each of, as applicable, its standardized approach capital conservation buffer, advanced approaches capital conservation buffer, and leverage buffer.

[2] A Board-regulated institution's "buffer requirement" means each of, as applicable, its standardized approach capital conservation buffer requirement, advanced approaches capital conservation buffer requirement, and leverage buffer requirement.

(d) *GSIB surcharge.* A global systemically important BHC must use its GSIB surcharge calculated in accordance with subpart H of this part for purposes of determining its maximum payout ratio under Table 2 to § 217.11(c)(4)(iii).

PART 225—BANK HOLDING COMPANIES AND CHANGE IN BANK CONTROL (REGULATION Y)

■ 3. The authority citation for part 225 continues to read as follows:

Authority: 12 U.S.C. 1817(j)(13), 1818, 1828(o), 1831i, 1831p–1, 1843(c)(8), 1844(b), 1972(1), 3106, 3108, 3310, 3331–3351, 3906, 3907, and 3909; 15 U.S.C. 1681s, 1681w, 6801 and 6805.

■ 4. Section 225.8 is revised to read as follows:

§ 225.8 Capital planning and stress capital buffer requirement.

(a) *Purpose.* This section establishes capital planning and prior notice and approval requirements for capital distributions by certain bank holding companies. This section also establishes the Board's process for determining the stress capital buffer requirement applicable to these bank holding companies.

(b) *Scope and reservation of authority*—(1) *Applicability.* Except as provided in paragraph (c) of this section, this section applies to:

(i) Any top-tier bank holding company domiciled in the United States with average total consolidated assets of $100 billion or more ($100 billion asset threshold);

(ii) Any other bank holding company domiciled in the United States that is made subject to this section, in whole or in part, by order of the Board;

(iii) Any U.S. intermediate holding company subject to this section pursuant to 12 CFR 252.153; and

(iv) Any nonbank financial company supervised by the Board that is made subject to this section pursuant to a rule or order of the Board.

(2) *Average total consolidated assets.* For purposes of this section, average total consolidated assets means the average of the total consolidated assets as reported by a bank holding company on its Consolidated Financial Statements for Holding Companies (FR Y–9C) for the four most recent consecutive quarters. If the bank holding company has not filed the FR Y–9C for each of the four most recent consecutive quarters, average total consolidated assets means the average of the company's total consolidated assets, as reported on the company's FR Y–9C, for the most recent quarter or consecutive quarters, as applicable. Average total consolidated assets are measured on the as-of date of the most recent FR Y–9C used in the calculation of the average.

(3) *Ongoing applicability.* A bank holding company (including any successor bank holding company) that is subject to any requirement in this section shall remain subject to such requirements unless and until its total consolidated assets fall below $100 billion for each of four consecutive quarters, as reported on the FR Y–9C and effective on the as-of date of the fourth consecutive FR Y–9C.

(4) *Reservation of authority.* Nothing in this section shall limit the authority of the Federal Reserve to issue or enforce a capital directive or take any other supervisory or enforcement action, including an action to address unsafe or unsound practices or conditions or violations of law.

(5) *Rule of construction.* Unless the context otherwise requires, any reference to bank holding company in this section shall include a U.S. intermediate holding company and shall include a nonbank financial company supervised by the Board to the extent this section is made applicable pursuant to a rule or order of the Board.

(6) *Application of this section by order.* The Board may apply this section, in whole or in part, to a bank holding company by order based on the institution's size, level of complexity, risk profile, scope of operations, or financial condition.

(c) *Transition periods for certain bank holding companies.* (1) A bank holding

company that meets the $100 billion asset threshold (as measured under paragraph (b) of this section) on or before September 30 of a calendar year must comply with the requirements of this section beginning on January 1 of the next calendar year, unless that time is extended by the Board in writing.

(2) A bank holding company that meets the $100 billion asset threshold after September 30 of a calendar year must comply with the requirements of this section beginning on January 1 of the second calendar year after the bank holding company meets the $100 billion asset threshold, unless that time is extended by the Board in writing.

(3) The Board, or the appropriate Reserve Bank with the concurrence of the Board, may require a bank holding company described in paragraph (c)(1) or (2) of this section to comply with any or all of the requirements of this section if the Board, or appropriate Reserve Bank with concurrence of the Board, determines that the requirement is appropriate on a different date based on the company's risk profile, scope of operation, or financial condition and provides prior notice to the company of the determination.

(d) *Definitions.* For purposes of this section, the following definitions apply:

(1) *Advanced approaches* means the risk-weighted assets calculation methodologies at 12 CFR part 217, subpart E, as applicable.

(2) *Average total nonbank assets* means the average of the total nonbank assets, calculated in accordance with the instructions to the FR Y–9LP, for the four most recent calendar quarters or, if the bank holding company has not filed the FR Y–9LP for each of the four most recent calendar quarters, for the most recent quarter or quarters, as applicable.

(3) *BHC baseline scenario* means a scenario that reflects the bank holding company's expectation of the economic and financial outlook, including expectations related to the bank holding company's capital adequacy and financial condition.

(4) *BHC stress scenario* means a scenario designed by a bank holding company that stresses the specific vulnerabilities of the bank holding company's risk profile and operations, including those related to the bank holding company's capital adequacy and financial condition.

(5) *Capital action* means any issuance of a debt or equity capital instrument, any capital distribution, and any similar action that the Federal Reserve determines could impact a bank holding company's consolidated capital.

(6) *Capital distribution* means a redemption or repurchase of any debt or equity capital instrument, a payment of common or preferred stock dividends, a payment that may be temporarily or permanently suspended by the issuer on any instrument that is eligible for inclusion in the numerator of any minimum regulatory capital ratio, and any similar transaction that the Federal Reserve determines to be in substance a distribution of capital.

(7) *Capital plan* means a written presentation of a bank holding company's capital planning strategies and capital adequacy process that includes the mandatory elements set forth in paragraph (e)(2) of this section.

(8) *Capital plan cycle* means the period beginning on January 1 of a calendar year and ending on December 31 of that year.

(9) *Capital policy* means a bank holding company's written principles and guidelines used for capital planning, capital issuance, capital usage and distributions, including internal capital goals; the quantitative or qualitative guidelines for capital distributions; the strategies for addressing potential capital shortfalls; and the internal governance procedures around capital policy principles and guidelines.

(10) *Common equity tier 1 capital* has the same meaning as under 12 CFR part 217.

(11) *Effective capital distribution limitations* means any limitations on capital distributions established by the Board by order or regulation, including pursuant to 12 CFR 217.11, 225.4, 252.63, 252.165, and 263.202, provided that, for any limitations based on risk-weighted assets, such limitations must be calculated using the standardized approach, as set forth in 12 CFR part 217, subpart D.

(12) *Final planned capital distributions* means the planned capital distributions included in a capital plan that include the adjustments made pursuant to paragraph (h) of this section, if any.

(13) *Global systemically important BHC* means a bank holding company identified as a global systemically important BHC under 12 CFR 217.402.

(14) *GSIB surcharge* has the same meaning as under 12 CFR 217.403.

(15) *Large and noncomplex bank holding company* means any bank holding company subject to this section that:

(i) Has, as of December 31 of the calendar year prior to the capital plan cycle:

(A) Average total consolidated assets of less than $250 billion;

(B) Average total nonbank assets of less than $75 billion; and

(ii) Is not a global systemically important BHC.

(16) *Nonbank financial company supervised by the Board* means a company that the Financial Stability Oversight Council has determined under section 113 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (12 U.S.C. 5323) shall be supervised by the Board and for which such determination is still in effect.

(17) *Planning horizon* means the period of at least nine consecutive quarters, beginning with the quarter preceding the quarter in which the bank holding company submits its capital plan, over which the relevant projections extend.

(18) *Regulatory capital ratio* means a capital ratio for which the Board has established minimum requirements for the bank holding company by regulation or order, including, as applicable, the bank holding company's regulatory capital ratios calculated under 12 CFR part 217 and the deductions required under 12 CFR 248.12; except that the bank holding company shall not use the advanced approaches to calculate its regulatory capital ratios.

(19) *Severely adverse scenario* has the same meaning as under 12 CFR part 252, subpart E.

(20) *Stress capital buffer requirement* means the amount calculated under paragraph (f) of this section.

(21) *Supervisory stress test* means a stress test conducted using a severely adverse scenario and the assumptions contained in 12 CFR part 252, subpart E.

(22) *U.S. intermediate holding company* means the top-tier U.S. company that is required to be established pursuant to 12 CFR 252.153.

(e) *Capital planning requirements and procedures*—(1) *Annual capital planning.* (i) A bank holding company must develop and maintain a capital plan.

(ii) A bank holding company must submit its complete capital plan to the Board and the appropriate Reserve Bank by April 5 of each calendar year, or such later date as directed by the Board or by the appropriate Reserve Bank with concurrence of the Board.

(iii) The bank holding company's board of directors or a designated committee thereof must at least annually and prior to submission of the capital plan under paragraph (e)(1)(ii) of this section:

(A) Review the robustness of the bank holding company's process for assessing capital adequacy;

(B) Ensure that any deficiencies in the bank holding company's process for

assessing capital adequacy are appropriately remedied; and

(C) Approve the bank holding company's capital plan.

(2) *Mandatory elements of capital plan.* A capital plan must contain at least the following elements:

(i) An assessment of the expected uses and sources of capital over the planning horizon that reflects the bank holding company's size, complexity, risk profile, and scope of operations, assuming both expected and stressful conditions, including:

(A) Estimates of projected revenues, losses, reserves, and pro forma capital levels, including regulatory capital ratios, and any additional capital measures deemed relevant by the bank holding company, over the planning horizon under a range of scenarios, including any scenarios provided by the Federal Reserve, the BHC baseline scenario, and at least one BHC stress scenario;

(B) A discussion of the results of any stress test required by law or regulation, and an explanation of how the capital plan takes these results into account; and

(C) A description of all planned capital actions over the planning horizon. Planned capital actions must be consistent with effective capital distribution limitations, except as may be adjusted pursuant to paragraph (h) of this section. In determining whether a bank holding company's planned capital distributions are consistent with effective capital distribution limitations, a bank holding company must assume that:

(*1*) Any countercyclical capital buffer amount currently applicable to the bank holding company remains at the same level, except that the bank holding company must reflect any increases or decreases in the countercyclical capital buffer amount that have been announced by the Board at the times indicated by the Board's announcement for when such increases or decreases will take effect; and

(*2*) Any GSIB surcharge currently applicable to the bank holding company when the capital plan is submitted remains at the same level, except that the bank holding company must reflect any increase in its GSIB surcharge pursuant to 12 CFR 217.403(d)(1), beginning in the fifth quarter of the planning horizon.

(ii) A detailed description of the bank holding company's process for assessing capital adequacy, including:

(A) A discussion of how the bank holding company will, under expected and stressful conditions, maintain capital commensurate with its risks, maintain capital above the regulatory capital ratios, and serve as a source of strength to its subsidiary depository institutions;

(B) A discussion of how the bank holding company will, under expected and stressful conditions, maintain sufficient capital to continue its operations by maintaining ready access to funding, meeting its obligations to creditors and other counterparties, and continuing to serve as a credit intermediary;

(iii) The bank holding company's capital policy; and

(iv) A discussion of any expected changes to the bank holding company's business plan that are likely to have a material impact on the bank holding company's capital adequacy or liquidity.

(3) *Data collection.* Upon the request of the Board or appropriate Reserve Bank, the bank holding company shall provide the Federal Reserve with information regarding:

(i) The bank holding company's financial condition, including its capital;

(ii) The bank holding company's structure;

(iii) Amount and risk characteristics of the bank holding company's on- and off-balance sheet exposures, including exposures within the bank holding company's trading account, other trading-related exposures (such as counterparty-credit risk exposures) or other items sensitive to changes in market factors, including, as appropriate, information about the sensitivity of positions to changes in market rates and prices;

(iv) The bank holding company's relevant policies and procedures, including risk management policies and procedures;

(v) The bank holding company's liquidity profile and management;

(vi) The loss, revenue, and expense estimation models used by the bank holding company for stress scenario analysis, including supporting documentation regarding each model's development and validation; and

(vii) Any other relevant qualitative or quantitative information requested by the Board or by the appropriate Reserve Bank to facilitate review of the bank holding company's capital plan under this section.

(4) *Resubmission of a capital plan.* (i) A bank holding company must update and resubmit its capital plan to the appropriate Reserve Bank within 30 calendar days of the occurrence of one of the following events:

(A) The bank holding company determines there has been or will be a material change in the bank holding company's risk profile, financial condition, or corporate structure since the bank holding company last submitted the capital plan to the Board and the appropriate Reserve Bank under this section; or

(B) The Board, or the appropriate Reserve Bank with concurrence of the Board, directs the bank holding company in writing to revise and resubmit its capital plan for any of the following reasons:

(*1*) The capital plan is incomplete or the capital plan, or the bank holding company's internal capital adequacy process, contains material weaknesses;

(*2*) There has been, or will likely be, a material change in the bank holding company's risk profile (including a material change in its business strategy or any risk exposure), financial condition, or corporate structure;

(*3*) The BHC stress scenario(s) are not appropriate for the bank holding company's business model and portfolios, or changes in financial markets or the macro-economic outlook that could have a material impact on a bank holding company's risk profile and financial condition require the use of updated scenarios; or

(*4*) For a bank holding company subject to paragraph (i) of this section, the capital plan or the condition of the bank holding company raise any of the issues described in paragraph (i)(2) of this section.

(ii) A bank holding company may resubmit its capital plan to the Federal Reserve if the Board or the appropriate Reserve Bank objects to the capital plan.

(iii) The Board, or the appropriate Reserve Bank with concurrence of the Board, may extend the 30-day period in paragraph (e)(4)(i) of this section for up to an additional 60 calendar days, or such longer period as the Board or the appropriate Reserve Bank, with concurrence of the Board, determines appropriate.

(iv) Any updated capital plan must satisfy all the requirements of this section; however, a bank holding company may continue to rely on information submitted as part of a previously submitted capital plan to the extent that the information remains accurate and appropriate.

(5) *Confidential treatment of information submitted.* The confidentiality of information submitted to the Board under this section and related materials shall be determined in accordance with applicable exemptions under the Freedom of Information Act (5 U.S.C. 552(b)) and the Board's Rules Regarding Availability of Information (12 CFR part 261).

(f) *Calculation of the stress capital buffer requirement*—(1) *General.* The Board will determine the stress capital buffer requirement that applies under 12 CFR 217.11 pursuant to paragraph (f) of this section.

(2) *Stress capital buffer requirement calculation.* A bank holding company's stress capital buffer requirement is equal to the greater of:

(i) The following calculation:

(A) The ratio of a bank holding company's common equity tier 1 capital to risk-weighted assets, as calculated under 12 CFR part 217, subpart D, as of the final quarter of the previous capital plan cycle, unless otherwise determined by the Board; minus

(B) The lowest projected ratio of the bank holding company's common equity tier 1 capital to risk-weighted assets, as calculated under 12 CFR part 217, subpart D, in any quarter of the planning horizon under a supervisory stress test; plus

(C) The ratio of:

(*1*) The sum of the bank holding company's planned common stock dividends (expressed as a dollar amount) for each of the fourth through seventh quarters of the planning horizon; to

(*2*) The risk-weighted assets of the bank holding company in the quarter in which the bank holding company had its lowest projected ratio of common equity tier 1 capital to risk-weighted assets, as calculated under 12 CFR part 217, subpart D, in any quarter of the planning horizon under a supervisory stress test; and

(ii) 2.5 percent.

(3) *Recalculation of stress capital buffer requirement.* If a bank holding company resubmits its capital plan pursuant to paragraph (e)(4) of this section, the Board may recalculate the bank holding company's stress capital buffer requirement. The Board will provide notice of whether the bank holding company's stress capital buffer requirement will be recalculated within 75 calendar days after the date on which the capital plan is resubmitted, unless the Board provides notice to the company that it is extending the time period.

(g) *Review of capital plans by the Federal Reserve.* The Board, or the appropriate Reserve Bank with concurrence of the Board, will consider the following factors in reviewing a bank holding company's capital plan:

(1) The comprehensiveness of the capital plan, including the extent to which the analysis underlying the capital plan captures and addresses potential risks stemming from activities across the bank holding company and the bank holding company's capital policy;

(2) The reasonableness of the bank holding company's capital plan, the assumptions and analysis underlying the capital plan, and the robustness of its capital adequacy process;

(3) Relevant supervisory information about the bank holding company and its subsidiaries;

(4) The bank holding company's regulatory and financial reports, as well as supporting data that would allow for an analysis of the bank holding company's loss, revenue, and reserve projections;

(5) The results of any stress tests conducted by the bank holding company or the Federal Reserve; and

(6) Other information requested or required by the Board or the appropriate Reserve Bank, as well as any other information relevant, or related, to the bank holding company's capital adequacy.

(h) *Federal Reserve notice of stress capital buffer requirement; final planned capital distributions*—(1) *Notice.* The Board will provide a bank holding company with notice of its stress capital buffer requirement and an explanation of the results of the supervisory stress test. Unless otherwise determined by the Board, notice will be provided by June 30 of the calendar year in which the capital plan was submitted pursuant to paragraph (e)(1)(ii) of this section or within 90 calendar days of receiving notice that the Board will recalculate the bank holding company's stress capital buffer requirement pursuant to paragraph (f)(3) of this section.

(2) *Response to notice*—(i) *Request for reconsideration of stress capital buffer requirement.* A bank holding company may request reconsideration of a stress capital buffer requirement provided under paragraph (h)(1) of this section. To request reconsideration of a stress capital buffer requirement, a bank holding company must submit to the Board a request pursuant to paragraph (j) of this section.

(ii) *Adjustments to planned capital distributions.* Within two business days of receipt of notice of a stress capital buffer requirement under paragraph (h)(1) or (j)(5) of this section, as applicable, a bank holding company must:

(A) Determine whether the planned capital distributions for the fourth through seventh quarters of the planning horizon under the BHC baseline scenario would be consistent with effective capital distribution limitations assuming the stress capital buffer requirement provided by the Board under paragraph (h)(1) or (j)(5) of this section, as applicable, in place of any stress capital buffer requirement in effect; and

(*1*) If the planned capital distributions for the fourth through seventh quarters of the planning horizon under the BHC baseline scenario would not be consistent with effective capital distribution limitations assuming the stress capital buffer requirement provided by the Board under paragraph (h)(1) or (j)(5) of this section, as applicable, in place of any stress capital buffer requirement in effect, the bank holding company must adjust its planned capital distributions such that its planned capital distributions would be consistent with effective capital distribution limitations assuming the stress capital buffer requirement provided by the Board under paragraph (h)(1) or (j)(5) of this section, as applicable, in place of any stress capital buffer requirement in effect; or

(*2*) If the planned capital distributions for the fourth through seventh quarters of the planning horizon under the BHC baseline scenario would be consistent with effective capital distribution limitations assuming the stress capital buffer requirement provided by the Board under paragraph (h)(1) or (j)(5) of this section, as applicable, in place of any stress capital buffer requirement in effect, the bank holding company may adjust its planned capital distributions. A bank holding company may not adjust its planned capital distributions to be inconsistent with the effective capital distribution limitations assuming the stress capital buffer requirement provided by the Board under paragraph (h)(1) or (j)(5) of this section, as applicable; and

(B) Notify the Board of any adjustments made to planned capital distributions for the fourth through seventh quarters of the planning horizon under the BHC baseline scenario.

(3) *Final planned capital distributions.* The Board will consider the planned capital distributions, including any adjustments made pursuant to paragraph (h)(2)(ii) of this section, to be the bank holding company's final planned capital distributions on the later of:

(i) The expiration of the time for requesting reconsideration under paragraph (j) of this section; and

(ii) The expiration of the time for adjusting planned capital distributions pursuant to paragraph (h)(2)(ii) of this section.

(4) *Effective date of final stress capital buffer requirement.* (i) The Board will provide a bank holding company with its final stress capital buffer requirement

and confirmation of the bank holding company's final planned capital distributions by August 31 of the calendar year that a capital plan was submitted pursuant to paragraph (e)(1)(ii) of this section, unless otherwise determined by the Board. A stress capital buffer requirement will not be considered final so as to be agency action subject to judicial review under 5 U.S.C. 704 during the pendency of a request for reconsideration made pursuant to paragraph (j) of this section or before the time for requesting reconsideration has expired.

(ii) Unless otherwise determined by the Board, a bank holding company's final planned capital distributions and final stress capital buffer requirement shall:

(A) Be effective on October 1 of the calendar year in which a capital plan was submitted pursuant to paragraph (e)(1)(ii) of this section; and

(B) Remain in effect until superseded.

(5) *Publication.* With respect to any bank holding company subject to this section, the Board may disclose publicly any or all of the following:

(i) The stress capital buffer requirement provided to a bank holding company under paragraph (h)(1) or (j)(5) of this section;

(ii) Adjustments made pursuant to paragraph (h)(2)(ii);

(iii) A summary of the results of the supervisory stress test; and

(iv) Other information.

(i) *Federal Reserve action on a capital plan* —(1) *Timing of action.* Board or the appropriate Reserve Bank with concurrence of the Board, will object, in whole or in part, to the capital plan or provide the bank holding company with a notice of non-objection to the capital plan:

(i) By June 30 of the calendar year in which a capital plan was submitted pursuant to paragraph (e)(1)(ii) of this section; and

(ii) For a capital plan resubmitted pursuant to paragraph (e)(4) of this section, within 75 calendar days after the date on which a capital plan is resubmitted, unless the Board provides notice to the company that it is extending the time period.

(2) *Basis for objection to a capital plan.* The Board, or the appropriate Reserve Bank with concurrence of the Board, may object to a capital plan submitted by a bank holding company that is not a large and noncomplex bank holding company if it determines that:

(i) Until January 1, 2021, except as provided in paragraph (i)(2)(ii) of this section, for a bank holding company that was subject to this section as of January 1, 2019, but whose capital plan has not been subject to review and a potential qualitative objection under the criteria listed in paragraph (i)(2)(i)(A) through (C) of this section for any period of four consecutive years:

(A) The bank holding company has material unresolved supervisory issues, including but not limited to issues associated with its capital adequacy process;

(B) The assumptions and analysis underlying the bank holding company's capital plan, or the bank holding company's methodologies and practices that support its capital planning process, are not reasonable or appropriate; or

(C) The bank holding company's capital planning process or proposed capital distributions otherwise constitute an unsafe or unsound practice, or would violate any law, regulation, Board order, directive, or condition imposed by, or written agreement with, the Board or the appropriate Reserve Bank. In determining whether a capital plan or any proposed capital distribution would constitute an unsafe or unsound practice, the Board or the appropriate Reserve Bank would consider whether the bank holding company is and would remain in sound financial condition after giving effect to the capital plan and all proposed capital distributions.

(ii) Notwithstanding paragraph (i)(2)(i) of this section, a bank holding company that was subject to this section as of January 1, 2019, and that receives a qualitative objection in the fourth year of the four-year period described in paragraph (i)(2)(i), pursuant to the criteria in paragraph (i)(2)(i)(A) through (C) of this section, will remain subject to a qualitative objection under this section until January 1 of the year after the first year in which the bank holding company does not receive a qualitative objection.

(3) *Notification of decision.* The Board or the appropriate Reserve Bank will notify the bank holding company in writing of the reasons for a decision to object to a capital plan.

(4) *Publication of summary results.* The Board may disclose publicly its decision to object or not object to a bank holding company's capital plan under this section. Any disclosure under this paragraph (i)(4) will occur by June 30 of the calendar year in which a capital plan was submitted pursuant to paragraph (e)(1)(ii) of this section, unless otherwise determined by the Board.

(j) *Administrative remedies; request for reconsideration.* The following requirements and procedures apply to any request under this paragraph (j):

(1) *General.* To request reconsideration of an objection to a capital plan, provided under paragraph (i) of this section, or of a stress capital buffer requirement, provided under paragraph (h) of this section, a bank holding company must submit a written request for reconsideration.

(2) *Timing of request.* (i) A request for reconsideration of an objection to a capital plan, provided under paragraph (i) of this section, must be received within 15 calendar days of receipt of a notice of objection to a capital plan.

(ii) A request for reconsideration of a stress capital buffer requirement, provided under paragraph (h) of this section, must be received within 15 calendar days of receipt of a notice of a bank holding company's stress capital buffer requirement.

(3) *Contents of request.* (i) A request for reconsideration must include a detailed explanation of why reconsideration should be granted (that is, why a stress capital buffer requirement or objection to a capital plan should be reconsidered). With respect to any information that was not previously provided to the Federal Reserve in the bank holding company's capital plan, the request should include an explanation of why the information should be considered.

(ii) A request for reconsideration may include a request for an informal hearing on the bank holding company's request for reconsideration.

(4) *Hearing.* (i) The Board may, in its sole discretion, order an informal hearing if the Board finds that a hearing is appropriate or necessary to resolve disputes regarding material issues of fact.

(ii) An informal hearing shall be held within 30 calendar days of a request, if granted, provided that the Board may extend this period upon notice to the requesting party.

(5) *Response to request.* (i) Within 30 calendar days of receipt of the bank holding company's request for reconsideration of an objection to a capital plan submitted under paragraph (j)(2) of this section or within 30 days of the conclusion of an informal hearing conducted under paragraph (j)(4) of this section, the Board will notify the company of its decision to affirm, modify, or withdraw the objection to the bank holding company's capital plan, or a specific capital distribution, provided that the Board may extend this period upon notice to the bank holding company.

(ii) Within 30 calendar days of receipt of the bank holding company's request for reconsideration of its stress capital buffer requirement submitted under

paragraph (j)(2) of this section or within 30 days of the conclusion of an informal hearing conducted under paragraph (j)(4) of this section, the Board will notify the company of its decision to affirm or modify the bank holding company's stress capital buffer requirement, provided that the Board may extend this period upon notice to the bank holding company.

(6) *Distributions during the pendency of a request for reconsideration.* During the pendency of the Board's decision under paragraph (j)(5) of this section, the bank holding company may make capital distributions that are consistent with effective distribution limitations, unless prior approval is required under paragraph (k)(1) of this section.

(k) *Approval requirements for certain capital actions*—(1) *Circumstances requiring approval*—(i) *Qualitative objection to and resubmission of a capital plan.* Unless it receives prior approval pursuant to paragraph (k)(3) of this section, a bank holding company may not make a capital distribution (excluding any capital distribution arising from the issuance of a capital instrument eligible for inclusion in the numerator of a regulatory capital ratio) under the following circumstances:

(A) The Board, or the appropriate Reserve Bank with the concurrence of the Board, objects to a capital plan and until such time as the Board, or the appropriate Reserve Bank with concurrence of the Board, issues a non-objection to the bank holding company's capital plan;

(B) The capital distribution would occur after the occurrence of an event requiring resubmission under paragraph (e)(4)(i)(A) or (B) of this section.

(ii) *Transition for certain planned capital actions.* For the period July 1, 2020, to September 30, 2020, a bank holding company is authorized to make capital distributions that do not exceed an amount equal to the average of capital distributions over the four quarters to which the Board or the appropriate Reserve Bank indicated its non-objection for the previous capital plan cycle. A bank holding company may request prior approval to make capital distributions in excess of the amount authorized for the period July 1, 2020, to September 30, 2020, pursuant to paragraph (k)(2) of this section.

(2) *Contents of request.* A request for a capital distribution under this section must contain the following information:

(i) The bank holding company's capital plan or a discussion of changes to the bank holding company's capital plan since it was last submitted to the Federal Reserve;

(ii) The purpose of the transaction;

(iii) A description of the capital distribution, including for redemptions or repurchases of securities, the gross consideration to be paid and the terms and sources of funding for the transaction, and for dividends, the amount of the dividend(s); and

(iv) Any additional information requested by the Board or the appropriate Reserve Bank (which may include, among other things, an assessment of the bank holding company's capital adequacy under a severely adverse scenario, a revised capital plan, and supporting data).

(3) *Approval of certain capital distributions.* (i) The Board, or the appropriate Reserve Bank with concurrence of the Board, will act on a request for prior approval of a capital distribution within 30 calendar days after the receipt of all the information required under paragraph (k)(2) of this section.

(ii) In acting on a request for prior approval of a capital distribution, the Board, or appropriate Reserve Bank with concurrence of the Board, will apply the considerations and principles in paragraphs (g) and (i) of this section, as appropriate. In addition, the Board, or the appropriate Reserve Bank with concurrence of the Board, may disapprove the transaction if the bank holding company does not provide all of the information required to be submitted under paragraph (k)(2) of this section.

(4) *Disapproval and hearing.* (i) The Board, or the appropriate Reserve Bank with concurrence of the Board, will notify the bank holding company in writing of the reasons for a decision to disapprove any proposed capital distribution. Within 15 calendar days after receipt of a disapproval by the Board, the bank holding company may submit a written request for a hearing.

(ii) The Board may, in its sole discretion, order an informal hearing if the Board finds that a hearing is appropriate or necessary to resolve disputes regarding material issues of fact. An informal hearing shall be held within 30 calendar days of a request, if granted, provided that the Board may extend this period upon notice to the requesting party.

(iii) Written notice of the final decision of the Board shall be given to the bank holding company within 60 calendar days of the conclusion of any informal hearing ordered by the Board, provided that the Board may extend this period upon notice to the requesting party.

(iv) While the Board's decision is pending and until such time as the Board, or the appropriate Reserve Bank with concurrence of the Board, approves the capital distribution at issue, the bank holding company may not make such capital distribution.

(l) *Post notice requirement.* A bank holding company must notify the Board and the appropriate Reserve Bank within 15 days of making a capital distribution if:

(1) The capital distribution was approved pursuant to paragraph (k)(3) of this section; or

(2) The dollar amount of the capital distribution will exceed the dollar amount of the bank holding company's final planned capital distributions, as measured on an aggregate basis beginning in the fourth quarter of the planning horizon through the quarter at issue.

PART 252—ENHANCED PRUDENTIAL STANDARDS (REGULATION YY)

■ 5. The authority citation for part 252 continues to read as follows:

Authority: 12 U.S.C. 321–338a, 481–486, 1467a, 1818, 1828, 1831n, 1831o, 1831p–l, 1831w, 1835, 1844(b), 1844(c), 3101 *et seq.,* 3101 note, 3904, 3906–3909, 4808, 5361, 5362, 5365, 5366, 5367, 5368, 5371.

Subpart E—Supervisory Stress Test Requirements for Certain U.S. Banking Organizations With $100 Billion or More in Total Consolidated Assets and Nonbank Financial Companies Supervised by the Board

■ 6. In § 252.16, republish paragraph (b) and add paragraphs (b)(1) through (3) to read as follows:

§ 252.16 Reports of stress test results.

* * * * *

(b) *Contents of reports.* The report required under paragraph (a) of this section must include the following information for the baseline scenario, severely adverse scenario, and any other scenario required under § 252.14(b)(3):

(1) A description of the types of risks being included in the stress test;

(2) A summary description of the methodologies used in the stress test; and

(3) For each quarter of the planning horizon, estimates of aggregate losses, pre-provision net revenue, provision for credit losses, net income, and regulatory capital ratios;

* * * * *

■ 7. In § 252.44, redesignate paragraph (c) as paragraph (d) and add new paragraph (c) to read as follows:

§ 252.44 Analysis conducted by the Board.

* * * * *

(c) In conducting a stress test under this section, the Board will make the

following assumptions regarding a covered company's capital actions over the planning horizon:

(1) The covered company will not pay any dividends on any instruments that qualify as common equity tier 1 capital;

(2) The covered company will make payments on instruments that qualify as additional tier 1 capital or tier 2 capital equal to the stated dividend, interest, or principal due on such instrument;

(3) The covered company will not make a redemption or repurchase of any capital instrument that is eligible for inclusion in the numerator of a regulatory capital ratio; and

(4) The covered company will not make any issuances of common stock or preferred stock.

* * * * *

Subpart F—Company-Run Stress Test Requirements for Certain U.S. Bank Holding Companies and Nonbank Financial Companies Supervised by the Board

■ 8. In § 252.54, revise paragraph (b)(2) to read as follows:

§ 252.54 Stress test.

* * * * *

(b) * * *

(2) *Additional components.* (i) The Board may require a covered company with significant trading activity to include a trading and counterparty component in its severely adverse scenario in the stress test required by this section. A covered company has significant trading activity if it has:

(A) Aggregate trading assets and liabilities of $50 billion or more, or aggregate trading assets and liabilities equal to 10 percent or more of total consolidated assets;

(B) Is not a large and noncomplex bank holding company as the term is used in 12 CFR 225.8.

(ii) The Board may require a covered company to include one or more additional components in its severely adverse scenario in the stress test required by this section based on the company's financial condition, size, complexity, risk profile, scope of operations, or activities, or risks to the U.S. economy.

* * * * *

■ 9. Section 252.56 is amended by revising paragraph (b) as follows:

§ 252.56 Methodologies and practices.

* * * * *

(b) *Assumptions regarding capital actions.* In conducting a stress test under § 252.54, a covered company is required to make the following assumptions regarding its capital actions over the planning horizon:

(1) The covered company will not pay any dividends on any instruments that qualify as common equity tier 1 capital;

(2) The covered company will make payments on instruments that qualify as additional tier 1 capital or tier 2 capital equal to the stated dividend, interest, or principal due on such instrument;

(3) The covered company will not make a redemption or repurchase of any capital instrument that is eligible for inclusion in the numerator of a regulatory capital ratio; and

(4) The covered company will not make any issuances of common stock or preferred stock.

* * * * *

■ 10. Appendix B to part 252 is amended by revising sections 2.6 and 2.7 and adding section 3.4 to read as follows:

Appendix B to Part 252—Stress Test Policy Statement

* * * * *

2.6. Incorporation of Business Plan Changes

(a) A firm's stress capital buffer requirement does not incorporate changes to its business plan that are likely to have a material impact on a covered company's capital adequacy and funding profile (material business plan changes). For example, planned issuances of common or preferred stock in connection with a planned merger or acquisition will not be included in the stress capital buffer requirement calculation. In addition, the common stock dividends attributable to issuances in connection with a planned merger or acquisition reflected in the covered company's pro-forma balance sheet estimates will also not be included in the stress capital buffer requirement calculation. Material business plan changes, including those resulting from a merger or acquisition, are incorporated into a covered company's capital and risk-weighted assets upon consummation of the transaction or occurrence of the change. As a result, the amount of capital required will adjust based on changes to the covered company's risk-weighted assets.

(b) If the material business plan change resulted in or would result in a material change in a covered company's risk profile, the company is required to resubmit its capital plan and the Board may determine to recalculate the stress capital buffer requirement based on the resubmitted capital plan.

2.7. Credit Supply Maintenance

(a) The supervisory stress test incorporates the assumption that aggregate credit supply does not contract during the stress period. The aim of supervisory stress testing is to assess whether firms are sufficiently capitalized to absorb losses during times of economic stress, while also meeting obligations and continuing to lend to households and businesses. The assumption that a balance sheet of consistent magnitude is maintained allows supervisors to evaluate the health of the banking sector assuming firms continue to lend during times of stress.

(b) In order to implement this policy, the Federal Reserve must make assumptions about new loan balances. To predict losses on new originations over the planning horizon, newly originated loans are assumed to have the same risk characteristics as the existing portfolio, where applicable, with the exception of loan age and delinquency status. These newly originated loans would be part of a covered company's normal business, even in a stressed economic environment. While an individual firm may assume that it reacts to rising losses by sharply restricting its lending (*e.g.,* by exiting a particular business line), the banking industry as a whole cannot do so without creating a ''credit crunch'' and substantially increasing the severity and duration of an economic downturn. The assumption that the magnitude of firm balance sheets will be fixed in the supervisory stress test ensures that covered companies cannot assume they will ''shrink to health,'' and serves the Federal Reserve's goal of helping to ensure that major financial firms remain sufficiently capitalized to accommodate credit demand in a severe downturn. In addition, by precluding the need to make assumptions about how underwriting standards might tighten or loosen during times of economic stress, the Federal Reserve follows the principle of consistency and comparability and promotes consistency across covered companies.

(c) In projecting the denominator for the calculation of the leverage ratio, the Federal Reserve will account for the effect of changes associated with the calculation of regulatory capital or changes to the Board's regulations.

* * * * *

3.4. Simple approach for projecting risk-weighted assets

(a) In projecting risk-weighted assets, the Federal Reserve will generally assume that a covered company's risk-weighted assets remain unchanged over the planning horizon. This assumption allows the Federal Reserve to independently project the risk-weighted assets of covered companies in line with the goal of simplicity (Principle 1.4). In addition, this approach is forward-looking (Principle 1.2), as this assumption removes reliance on historical data and past outcomes from the projection of risk-weighted assets.

(b) In projecting a firm's risk-weighted assets, the Federal Reserve will account for the effect of changes associated with the calculation of regulatory capital or changes to the Board's regulations in the calculation of risk-weighted assets.

By order of the Board of Governors of the Federal Reserve System, March 5, 2020.

Ann Misback,

Secretary of the Board.

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Part III

Environmental Protection Agency

40 CFR Part 63

National Emission Standards for Hazardous Air Pollutants: Solvent Extraction for Vegetable Oil Production Residual Risk and Technology Review; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2019–0208; FRL–10006–06–OAR]

RIN 2060–AU17

National Emission Standards for Hazardous Air Pollutants: Solvent Extraction for Vegetable Oil Production Residual Risk and Technology Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This action finalizes the residual risk and technology review (RTR) conducted for the Solvent Extraction for Vegetable Oil Production source category regulated under national emission standards for hazardous air pollutants (NESHAP). Based on the results of the U.S. Environmental Protection Agency's (EPA's) risk review, the Agency is finalizing the decision that risks due to emissions of air toxics from this source category are acceptable and that the current NESHAP provides an ample margin of safety to protect public health. Under the technology review, the EPA is finalizing the decision that there are no developments in practices, processes, or control technologies that necessitate revision of the standards. Therefore, the EPA is finalizing no revisions to the numerical emission limits based on the risk and technology reviews. We are taking final action to correct and clarify regulatory provisions related to emissions during periods of startup, shutdown, and malfunction (SSM), including removing general exemptions for periods of SSM, adding alternative work practice standards for periods of initial startup for new or significantly modified sources, and making other minor clarifications or corrections. The EPA is also taking final action to add provisions for electronic reporting of certain notifications and reports and performance test results; and make other minor clarifications and corrections. These final amendments will result in improved compliance and implementation of the rule.

DATES: This final rule is effective on March 18, 2020.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2019–0208. All documents in the docket are listed on the *https://www.regulations.gov/* website. Although listed, 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 either electronically through *https://www.regulations.gov/,* or in hard copy at the EPA Docket Center, WJC West Building, Room Number 3334, 1301 Constitution Ave., NW, Washington, DC. The Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m. Eastern Standard Time (EST), Monday through Friday. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the EPA Docket Center is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: For questions about this final action, contact Mr. Bill Schrock, Natural Resources Group, Sector Policies and Programs Division (E143–03), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–5032; fax number: (919) 541–0516; and email address: *schrock.bill@epa.gov.* For specific information regarding the risk modeling methodology, contact Mr. Matthew Woody, Health and Environmental Impacts Division (C539–02), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–1535; fax number: (919) 541–0840; and email address: *woody.matthew@epa.gov.* For information about the applicability of the NESHAP to a particular entity, contact Ms. Maria Malave, Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency, WJC South Building (Mail Code 2227A), 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number: (202) 564–7027; and email address: *malave.maria@epa.gov.*

SUPPLEMENTARY INFORMATION:

Preamble acronyms and abbreviations. We use multiple acronyms and terms in this preamble. While this list may not be exhaustive, to ease the reading of this preamble and for reference purposes, the EPA defines the following terms and acronyms here:

CAA Clean Air Act
CBI Confidential Business Information
CDX Central Data Exchange
CEDRI Compliance and Emissions Data Reporting Interface
CFR Code of Federal Regulations
EPA Environmental Protection Agency
HAP hazardous air pollutant(s)
HI hazard index
HQ hazard quotient
ICR Information Collection Request
km kilometer
MACT maximum achievable control technology
MIR maximum individual risk
NAICS North American Industry Classification System
NESHAP national emission standards for hazardous air pollutants
NTTAA National Technology Transfer and Advancement Act
OMB Office of Management and Budget
PRA Paperwork Reduction Act
REL reference exposure level
RFA Regulatory Flexibility Act
RTR residual risk and technology review
SSM startup, shutdown, and malfunction
the Court United States Court of Appeals for the District of Columbia Circuit
TOSHI target organ-specific hazard index
tpy tons per year
UMRA Unfunded Mandates Reform Act
VCS voluntary consensus standards

Background information. On June 27, 2019, the EPA proposed revisions to the Solvent Extraction for Vegetable Oil Production NESHAP in conjunction with our RTR for the Solvent Extraction for Vegetable Oil Production source category (84 FR 30812). In this action, we are finalizing decisions and revisions for the rule. We summarize some of the more significant comments we timely received regarding the proposed rule and provide our responses in this preamble. A summary of all other public comments on the proposal and the EPA's responses to those comments is available in the *Summary of Public Comments and Responses for the Risk and Technology Review for Solvent Extraction For Vegetable Oil Production,* in Docket ID No. EPA–HQ–OAR–2019–0208. A ''track changes'' version of the regulatory language that incorporates the changes in this action is available in the docket.

Organization of this document. The information in this preamble is organized as follows:

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K. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations
L. Congressional Review Act (CRA)

I. General Information

A. Does this action apply to me?

Regulated entities. Categories and entities potentially regulated by this action are shown in Table 1 of this preamble.

TABLE 1—NESHAP AND INDUSTRIAL SOURCE CATEGORIES AFFECTED BY THIS FINAL ACTION

Source category	NESHAP	NAICS [a] code
Flour Milling	Solvent Extraction for Vegetable Oil Production	311211
Wet Corn Milling		311221
Fats and Oils Refining and Blending		311225
Other Animal Food Manufacturing		311119
Soybean and Other Oilseed Processing		311224
Fats and Oils Refining and Blending		311225

[a] North American Industry Classification System.

Table 1 of this preamble is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by the final action for the source category listed. To determine whether your facility is affected, you should examine the applicability criteria in the appropriate NESHAP. If you have any questions regarding the applicability of any aspect of this NESHAP, please contact the appropriate person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section of this preamble.

B. Where can I get a copy of this document and other related information?

In addition to being available in the docket, an electronic copy of this final action will also be available on the internet. Following signature by the EPA Administrator, the EPA will post a copy of this final action at: *https://www.epa.gov/stationary-sources-air-pollution/solvent-extraction-vegetable-oil-production-national-emission.* Following publication in the **Federal Register**, the EPA will post the **Federal Register** version and key technical documents at this same website.

Additional information is available on the RTR website at *https://www.epa.gov/stationary-sources-air-pollution/risk-and-technology-review-national-emissions-standards-hazardous.* This information includes an overview of the RTR program and links to project websites for the RTR source categories.

C. Judicial Review and Administrative Reconsideration

Under Clean Air Act (CAA) section 307(b)(1), judicial review of this final action is available only by filing a petition for review in the United States Court of Appeals for the District of Columbia Circuit (the Court) by May 18, 2020. Under CAA section 307(b)(2), the requirements established by this final rule may not be challenged separately in any civil or criminal proceedings brought by the EPA to enforce the requirements.

Section 307(d)(7)(B) of the CAA further provides that only an objection to a rule or procedure which was raised with reasonable specificity during the period for public comment (including any public hearing) may be raised during judicial review. This section also provides a mechanism for the EPA to reconsider the rule if the person raising an objection can demonstrate to the Administrator that it was impracticable to raise such objection within the period for public comment or if the grounds for such objection arose after the period for public comment (but within the time specified for judicial review) and if such objection is of central relevance to the outcome of the rule. Any person seeking to make such a demonstration should submit a Petition for Reconsideration to the Office of the Administrator, U.S. EPA, Room 3000, WJC South Building, 1200 Pennsylvania Ave. NW, Washington, DC 20460, with a copy to both the person(s) listed in the preceding **FOR FURTHER INFORMATION CONTACT** section, and the Associate General Counsel for the Air and Radiation Law Office, Office of General Counsel (Mail Code 2344A), U.S. EPA, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

II. Background

A. What is the statutory authority for this action?

Section 112 of the CAA establishes a two-stage regulatory process to address emissions of hazardous air pollutants (HAP) from stationary sources. In the first stage, we must identify categories of sources emitting one or more of the HAP listed in CAA section 112(b) and then promulgate technology-based NESHAP for those sources. ''Major sources'' are those that emit, or have the potential to emit, any single HAP at a rate of 10 tons per year (tpy) or more, or 25 tpy or more of any combination of HAP. For major sources, these standards are commonly referred to as maximum achievable control technology (MACT) standards and must reflect the maximum degree of emission reductions of HAP achievable (after considering cost, energy requirements, and non-air quality health and environmental impacts). In developing MACT standards, CAA section 112(d)(2) directs the EPA to consider the application of measures, processes, methods, systems, or techniques, including, but not limited to, those that reduce the volume of or eliminate HAP emissions through process changes, substitution of materials, or other modifications; enclose systems or processes to eliminate emissions; collect, capture, or treat HAP when released from a process, stack, storage, or fugitive emissions point; are design, equipment, work practice, or operational standards; or any combination of the above.

For these MACT standards, the statute specifies certain minimum stringency requirements, which are referred to as MACT floor requirements, and which may not be based on cost considerations (see CAA section 112(d)(3)). For new sources, the MACT floor cannot be less stringent than the emission control achieved in practice by the best-controlled similar source. The MACT standards for existing sources can be less stringent than floors for new sources, but they cannot be less stringent than the average emission limitation achieved by the best-performing 12 percent of existing sources in the category or subcategory (or the best-performing five sources for categories or subcategories with fewer than 30 sources). In developing MACT standards, we must also consider control options that are more stringent than the floor under CAA section 112(d)(2). We may establish standards more stringent than the floor, based on the consideration of the cost of achieving the emissions reductions, any non-air quality health and environmental impacts, and energy requirements.

In the second stage of the regulatory process, the CAA requires the EPA to undertake two different analyses, which we refer to as the technology review and the residual risk review. Under the technology review, we must review the technology-based standards and revise them ''as necessary (taking into account developments in practices, processes, and control technologies)'' no less frequently than every 8 years, pursuant to CAA section 112(d)(6). Under the residual risk review, we must evaluate the risk to public health remaining after application of the technology-based standards and revise the standards, if necessary, to provide an ample margin of safety to protect public health or to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect. The residual risk review is required within 8 years after promulgation of the technology-based standards, pursuant to CAA section 112(f). In conducting the residual risk review, if the EPA determines that the current standards provide an ample margin of safety to protect public health, it is not necessary to revise the MACT standards pursuant to CAA section 112(f).[1] For more information on the statutory authority for this rule, see 84 FR 30812, June 27, 2019.

B. What is the Solvent Extraction for Vegetable Oil Production source category and how does the NESHAP regulate HAP emissions from the source category?

The EPA promulgated the Solvent Extraction for Vegetable Oil Production NESHAP on April 12, 2001 (66 FR 19006). The standards are codified at 40 CFR part 63, subpart GGGG. As promulgated in 2001 and further amended on April 5, 2002 (67 FR 16317), and September 1, 2004 (69 FR 53338), the NESHAP regulates HAP emissions from solvent extraction for vegetable oil production processes at a facility that is a major source of HAP emissions. The affected source is each vegetable oil production process. A vegetable oil production process means the equipment comprising a continuous process for producing crude vegetable oil and meal products, including specialty soybean products, in which oil is removed from oilseeds listed in Table 1 of 40 CFR 63.2840 through direct contact with an organic solvent. Process equipment typically includes the following components: oilseed preparation operations (including conditioning, drying, dehulling, and cracking), solvent extractors, desolventizer-toasters, meal dryers, meal coolers, meal conveyor systems, oil distillation units, solvent evaporators and condensers, solvent recovery system (also referred to as a mineral oil absorption system), vessels storing solvent-laden materials, and crude meal packaging and storage vessels. A vegetable oil production process does not include vegetable oil refining operations (including operations such as bleaching, hydrogenation, and deodorizing) and operations that engage in additional chemical treatment of crude soybean meals produced in specialty desolventizer units (including operations such as soybean isolate production). The source category covered by this MACT standard currently includes 89 facilities.

The primary HAP emitted from vegetable oil production processes is n-hexane. The EPA does not consider n-hexane classifiable as a human carcinogen. However, short-term exposure to n-hexane can cause reactions such as irritation, dizziness, headaches, and nausea. Long-term exposure can cause permanent nerve damage.

The current NESHAP controls facility-wide n-hexane emissions by setting emission limitations based on the number of gallons of HAP lost per ton of oilseeds processed, expressed as oilseed solvent loss ratios. Facilities demonstrate compliance by calculating a compliance ratio comparing the actual HAP loss to the allowable HAP loss for the previous 12 operating months. Allowable HAP loss is based on the oilseed solvent loss ratios provided in Table 1 of 40 CFR 63.2840 of the rule for new and existing sources. Compliance is demonstrated when the facility's calculated compliance ratio is less than or equal to 1.00 (*i.e.,* the actual HAP loss is no greater than the calculated allowable HAP loss). Determination of compliance with the requirements of the Solvent Extraction for Vegetable Oil Production NESHAP requires the facility to keep records of the amount of n-hexane purchased, used, and recovered from the oilseed extraction process, the amount of oilseed processed, and the volume fraction of each HAP exceeding 1 percent in the extraction solvent used. Facilities may also adjust their solvent loss to account for cases where solvent is routed through a closed vent system

[1] The Court has affirmed this approach of implementing CAA section 112(f)(2)(A): *NRDC* v. *EPA,* 529 F.3d 1077, 1083 (DC Cir. 2008) (''If EPA determines that the existing technology-based standards provide an 'ample margin of safety,' then the Agency is free to readopt those standards during the residual risk rulemaking.'').

to a control device that is used to reduce emissions to meet the standard.

C. What changes did we propose for the Solvent Extraction for Vegetable Oil Production source category in our June 27, 2019, RTR proposal?

On June 27, 2019, the EPA published a proposed rule in the **Federal Register** for the Solvent Extraction for Vegetable Oil Production NESHAP, 40 CFR part 63, subpart GGGG, that took into consideration the RTR analyses. In the proposed rule, we proposed that the risks from the source category are acceptable and the current standards provide an ample margin of safety to protect public health. In addition, pursuant to the technology review for the Solvent Extraction for Vegetable Oil Production source category, we proposed no revisions to the current standards based on these analyses.

We proposed revisions to the SSM provisions of the standards to ensure that they are consistent with the Court decision in *Sierra Club* v. *EPA,* 551 F. 3d 1019 (D.C. Cir. 2008). Specifically, the Court vacated the SSM exemption contained in 40 CFR 63.6(f)(1) and 40 CFR 63.6(h)(1), holding that under section 302(k) of the CAA, emissions standards or limitations must be continuous in nature and that the SSM exemption violates the CAA's requirement that some CAA section 112 standards apply continuously. We therefore proposed that the standards would apply at all times, including during startups, shutdowns, and malfunctions (see 40 CFR 63.2840(a) and Table 1 to 40 CFR 63.2870 (General Provisions Applicability Table). Additionally, we proposed to remove requirements that allowed sources to previously designate a source operating status period as a ''malfunction period'' and exclude data collected during the ''malfunction period'' when determining compliance with the emission standards.[2] Under the proposed rule, sources that continue to operate must instead meet the emission standard requirements for either a normal operating period or the work practice standards for an initial startup period (if applicable) in 40 CFR 63.2850 and Table 1 of 40 CFR 63.2850. In proposing the revised standards, the EPA considered whether to set separate standards for startup and shutdown periods, but only found that separate standards were necessary for initial startup periods for new or significantly modified sources. For periods of initial startup following new construction or significant modification, we proposed work practice standards and a requirement to establish and follow site-specific operating ranges for temperature and vacuum for the desolventizing and oil distillation units associated with solvent recovery, as well as associated recordkeeping and reporting requirements (*e.g.,* initial startup report) for these periods.

We proposed to require electronic reporting of initial notifications, initial startup reports, annual compliance certifications, deviation reports, and performance test reports through the EPA's Central Data Exchange (CDX) using the Compliance and Emissions Data Reporting Interface (CEDRI). We also proposed minor clarifications and corrections to five definitions (*i.e.,* ''Compliance ratio,'' ''Nonoperating period,'' ''Normal operating period,'' ''Operating month,'' and ''Hazardous air pollutant (HAP)'') and to 40 CFR 63.2840(a)(1) and (b)(1), 40 CFR 63.2853(a)(2), 40 CFR 63.2855(a)(3), and Table 1 of 40 CFR 63.2850. Refer to section IV.D of the June 27, 2019, proposal preamble for further discussion of these proposed amendments and the EPA's rationale for these changes (84 FR 60825).

III. What is included in this final rule?

This action finalizes the EPA's determinations pursuant to the RTR provisions of CAA section 112 for the Solvent Extraction for Vegetable Oil Production source category. This action also finalizes other changes to the NESHAP, including revisions to the SSM provisions of the MACT rule in order to ensure that they are consistent with the Court decision in *Sierra Club* v. *EPA,* 551 F. 3d 1019 (D.C. Cir. 2008), provisions for electronic reporting of initial notifications, initial startup reports, annual compliance certifications, deviation reports, and performance test reports; and other minor editorial and technical changes. This action reflects several changes to the proposed rule in consideration of comments received during the public comment period as described in section IV of this preamble.

A. What are the final rule amendments based on the risk review for the Solvent Extraction for Vegetable Oil Production source category?

This section describes the final risk determination for the Solvent Extraction for Vegetable Oil Production NESHAP being promulgated pursuant to CAA section 112(f). The EPA proposed no changes to the Solvent Extraction for Vegetable Oil Production NESHAP based on the risk review conducted pursuant to CAA section 112(f). In this action, we are finalizing our proposed determination that risks from this source category are acceptable, and that the standards provide an ample margin of safety to protect public health and prevent an adverse environmental effect. Section IV.A.3 of this preamble provides a summary of key comments we received regarding the risk review and our responses to those comments.

B. What are the final rule amendments based on the technology review for the Solvent Extraction for Vegetable Oil Production source category?

The EPA is finalizing the technology review as proposed. We determined that there are no developments in practices, processes, and control technologies that warrant revisions to the MACT standards for this source category. Therefore, we are not finalizing revisions to the MACT standards under CAA section 112(d)(6).

C. What are the final rule amendments addressing emissions during periods of SSM?

We are finalizing the proposed amendments to the Solvent Extraction for Vegetable Oil Production NESHAP to remove and revise provisions related to SSM. As detailed in section IV.D of the proposal preamble (84 FR 30825), the final amendments to the Solvent Extraction for Vegetable Oil Production NESHAP require that the standards apply at all times (see 40 CFR 63.2840(a) and Table 1 to 40 CFR 63.2870 (General Provisions applicability table), consistent with the Court decision in *Sierra Club* v. *EPA,* 551 F. 3d 1019 (D.C. Cir. 2008).

We are finalizing that the emission standards for normal operation apply at all times, except for periods of initial

[2] The 2001 NESHAP allowed for facilities to determine compliance based on the distinct categorized operating status of the facility (normal operating, nonoperating, initial startup, malfunction, or exempt) during a compliance period, as defined in Table 1 of 40 CFR 63.2853. Existing and new sources operating during a malfunction period could either meet the compliance requirements for normal operation periods in 40 CFR 63.2850 and Table 1 of 40 CFR 63.2850 or the requirements for malfunction periods subject to 40 CFR 63.2850(e)(2) and Table 1 of 40 CFR 63.2850 (for which no limits or work practices applied). Sources operating during a malfunction period were not required to determine compliance using data recorded for the malfunction period. We proposed to remove the option for facilities to categorize the operating period as a malfunction period and to remove the option to meet the requirements for malfunction periods subject to 40 CFR 63.2850(e)(2) and Table 1 of 40 CFR 63.2850, such that the standards apply at all times. Sources that continue to operate during a malfunction must continue to meet the general duty requirements at 40 CFR 63.2840(g). The term ''malfunction period'' is retained in the rule only as it applies to facilities prior to September 15, 2020.

startup for new and significantly modified sources, as described below in this section and in section IV.C of this preamble. For periods of initial startup for new or significantly modified sources, we are finalizing work practice standards, including operation of the mineral oil absorption system and solvent condensers at all times during the initial startup period, and a requirement to establish and follow site-specific operating ranges for temperature and vacuum for the desolventizing and oil distillation units associated with solvent recovery, as well as associated recordkeeping and reporting requirements (*e.g.,* initial startup report) for these periods. Facilities will continue to have the option to meet the requirements for normal operating periods in Table 1 of 40 CFR 63.2850. The EPA is also finalizing the definition of ''initial startup period'' and the requirements of 40 CFR 62.2850(c)(2) and (d)(2) to clarify that the end of the initial startup period occurs when the plant meets and maintains steady-state operations. Steady-state is defined as operating at or above 90 percent of the extractor nominal design production rate or at or above 90 percent of the production rate in the plant's permit for 15 consecutive days. Any initial startup period may not exceed 6 calendar months after startup for new or reconstructed sources or 3 calendar months after startup for modified sources.

As discussed in section IV.D of the June 27, 2019, proposal preamble, the EPA interprets CAA section 112 as not requiring emissions that occur during periods of malfunction to be factored into development of CAA section 112 standards, although the EPA has the discretion to set standards for malfunctions where feasible. We noted that our interpretation regarding CAA section 112 not requiring emissions that occur during periods of malfunction to be factored into development of CAA section 112 standards has been upheld as reasonable by the Court in *U.S. Sugar Corp.* v. *EPA,* 830 F.3d 579, 606–610 (2016). The EPA further explained that, ''EPA will consider whether circumstances warrant setting standards for a particular type of malfunction and, if so, whether the EPA has sufficient information to identify the relevant best performing sources and establish a standard for such malfunctions'' (84 FR 30827).

While we requested comment on work practice standards during periods of malfunction, and received some information in support of such standards, we did not receive sufficient information on which to base a malfunction standard. As further explained at proposal, ''[i]n the event that a source fails to comply with the applicable CAA section 112(d) standards as a result of a malfunction event, the EPA would determine an appropriate response based on, among other things, the good faith efforts of the source to minimize emissions during malfunction periods, including preventive and corrective actions, as well as root cause analyses to ascertain and rectify excess emissions. The EPA would also consider whether the source's failure to comply with the CAA section 112(d) standard was, in fact, sudden, infrequent, not reasonably preventable and was not instead caused in part by poor maintenance or careless operation. 40 CFR 63.2 (definition of malfunction). If the EPA determines in a particular case that an enforcement action against a source for violation of an emission standard is warranted, the source can raise any and all defenses in that enforcement action and the Federal district court will determine what, if any, relief is appropriate. The same is true for citizen enforcement actions. Similarly, the presiding officer in an administrative proceeding can consider any defense raised and determine whether administrative penalties are appropriate'' (84 FR 30828).

For these reasons, we are not setting separate standards for periods of malfunction. Under the final rule, sources that experience an unscheduled shutdown as a result of a malfunction, continue to operate during a malfunction (including the period reasonably necessary to correct the malfunction), or start up after a shutdown resulting from a malfunction must instead meet the emission standard requirements for either a normal operating period or the work practice standards for an initial startup period (if a new or significantly modified source) in 40 CFR 63.2850 and Table 1 of 40 CFR 63.2850. Although we did not propose and are not finalizing work practice standards for periods of malfunction, we are finalizing revisions to deviation reporting to account for one-time malfunction events in which the potential solvent loss could result in a deviation for one or more consecutive monthly compliance ratio determinations. Specifically, we have revised the final rule to include a requirement that facilities flag and provide an explanation for any deviation from the compliance ratio for which a deviation report is being submitted for more than one consecutive month (*i.e.,* include a reference to the original date and reporting of the deviation). Although a facility would need to retain records of any deviation and the corrective action(s) performed, no additional corrective action would be required at the time the 12-month compliance ratio is officially exceeded in subsequent months if the facility demonstrates the exceedance is from a prior malfunction that has been corrected.

As is explained in more detail below, we are finalizing revisions related to requirements that apply during periods of SSM. We eliminated or revised certain recordkeeping and reporting requirements related to the eliminated SSM exemption. The EPA also made changes to the rule to remove or modify inappropriate, unnecessary, or redundant language in the absence of the SSM exemption. Refer to sections III.C.1 through III.C.6 of this preamble for a detailed discussion of the final amendments.

1. 40 CFR 63.2840 General Duty

We are finalizing as proposed revisions to the General Provisions applicability table (Table 1 to 40 CFR 63.2870) entry for 40 CFR 63.6(e)(1)(i) by changing the ''Yes'' in column 4 to a ''No.'' The EPA is instead adding general duty regulatory text at 40 CFR 63.2840(g) to reflect the general duty to minimize emissions while eliminating the reference to periods covered by an SSM exemption. The general duty to minimize emissions continues to apply during periods of malfunction and sources must still address malfunctions expeditiously in order to maintain any affected source, including associated air pollution control equipment and monitoring equipment, and minimize emissions. The EPA is also revising the General Provisions applicability table (Table 1 to 40 CFR 63.2870) entry for 40 CFR 63.6(e)(1)(ii) by changing the ''Yes'' in column 4 to a ''No'' to remove requirements that are not necessary with the elimination of the SSM exemption or are redundant with the general duty requirement being added at 40 CFR 63.2840(g).

2. SSM Plan

As proposed, the EPA is revising the General Provisions applicability table (Table 1 to 40 CFR 63.2870) entries for 40 CFR 63.6(e)(3)(i) through (e)(3)(ii), 40 CFR 63.6(e)(3)(v) through (vii), and 40 CFR 63.6(e)(3)(viii) and (ix) by changing the ''Yes'' in column 4 to a ''No.'' The EPA is also revising 40 CFR 63.2852, which cross-references the requirements of 40 CFR 63.6(e)(3). The final amendments remove requirements related to the SSM plan.

3. Compliance With Standards

The EPA is revising the General Provisions applicability table (Table 1 to 40 CFR 63.2870) entry for 40 CFR 63.6(f)(1) by revising the text in column 4 and removing the text in column 5 to clarify that the SSM exemption previously applied but will not apply going forward.

4. 40 CFR 63.2853 Performance Testing

We are also finalizing a revision to the performance testing requirements. The EPA is revising the General Provisions applicability table (Table 1 to 40 CFR 63.2870) entry for 40 CFR 63.7(e)(1) by changing the ''Yes'' in column 4 to a ''No,'' and adding a revised performance testing requirement at 40 CFR 63.2853(a)(5)(i)(A). The final performance testing provisions prohibit performance testing for purposes of demonstrating compliance during startup, shutdown, or malfunction because these conditions are not representative of normal operating periods. The final rule also requires that operators maintain records to document that operating conditions during the test represent normal operations.

5. 40 CFR 63.2862 Recordkeeping

The EPA is revising the General Provisions applicability table (Table 1 to 40 CFR 63.2870) entry for 40 CFR 63.10(b)(2)(i) by changing the ''Yes'' in column 4 to a ''No,'' and is adding recordkeeping requirements to 40 CFR 63.2862(f). The final revisions require owners or operators of sources subject to a work practice standard during initial startup times to report a description and dates of the initial startup period, the reason it qualifies as an initial startup period, an estimate of the solvent loss in gallons for the duration of the initial startup, and the nominal design rate and operating rate of the extractor or the permitted and actual production rates for the duration of the initial startup period. The final revisions also require facilities to record information including the measured temperature and pressure for desolventizing and oil distillation units; an indication that the mineral oil absorption system was operating at all times; and (3) an indication that the solvent condensers were operating at all times.

The EPA is revising the General Provisions applicability table (Table 1 to 40 CFR 63.2870) entry for 40 CFR 63.10(b)(2)(ii) by changing the ''Yes'' in column 4 to a ''No.'' The final rule includes recordkeeping requirements for malfunctions in 40 CFR 63.2862(g), including any ''failure to meet an applicable standard'' (including any deviation from the emissions standards of 40 CFR 63.2840 or the work practice standards for periods of initial startup). Source owners or operators must record the date and duration of the ''failure.'' We have revised the final rule requirements from proposal to clarify how to designate the date a deviation occurred and the duration of the deviation. For deviations from the compliance ratio, the date of the deviation is the date the compliance ratio determination is made, and the duration of the deviation is the length of time taken to address the cause of the deviation (including the duration of any malfunction) and to return the affected unit(s) to its normal or usual manner of operation. For deviations from the work practice standard during the initial startup period, the date of the deviation is the date when the facility fails to comply with any of the work practice standards in 40 CFR 63.2840(h), and the duration of the deviation is the length of time taken to return to the work practice standards. We have also removed the requirement to record and report the time of the deviation as described in section IV.C of this preamble.

The EPA is adding to 40 CFR 63.2862(g) a requirement that source owners or operators keep records that include a statement of the cause of each deviation (including unknown cause, if applicable), a list of the affected source or equipment and actions taken to minimize emissions, an estimate of the quantity of each regulated pollutant emitted over the standard when the standard is not met, and a description of the method used to estimate the emissions.

The EPA is revising the General Provisions applicability table (Table 1 to 40 CFR 63.2870) entry for 40 CFR 63.10(b)(2)(iv) and 40 CFR 63.10(b)(2)(v) by changing the ''Yes'' in column 4 to a ''No'' to remove requirements related to the SSM plan. The final rule includes a requirement to record actions to minimize emissions and record corrective actions in 40 CFR 63.2862(g).

6. 40 CFR 63.2861 Reporting

To replace the SSM reporting requirements, the EPA is eliminating the periodic SSM reports in 40 CFR 63.2861(c), which were required to be submitted at the end of each calendar month of an initial startup period or malfunction period. The EPA is also removing the requirement in 40 CFR 63.2861(d) to submit an immediate report for SSM when a source failed to meet an applicable standard but did not follow the SSM plan. The EPA is instead requiring that existing or new source owners or operators that fail to meet the applicable emission standards (including sources that experience a malfunction) or the work practice standards for initial startup periods at any time must report the information concerning such events in the deviation report, including the number, date, duration, and the cause of such events (including unknown cause, if applicable), a list of the affected source or equipment, an estimate of the quantity of HAP emitted over the emission requirements of 40 CFR 63.2840, and a description of the method used to estimate the emissions. For sources operating under an initial startup period, the EPA is also finalizing a provision that source owners or operators that fail to meet the work practice standard must include a description of the deviation and include the records for the initial startup period in 40 CFR 63.2862(f).

Finally, the EPA is finalizing that source owners or operators that choose to operate under an initial startup period according to 40 CFR 63.2850(c)(2) or (d)(2) must also provide an initial startup report, including a compliance certification indicating whether the source was in compliance with the work practice standard of 40 CFR 63.2840(h). The initial report must be submitted within 30 days of the end of the initial startup period.

The legal rationale and detailed changes for SSM periods that we are finalizing here are set forth in the proposed rule (see 84 FR 30825). Section IV.C of this preamble provides a summary of key comments we received on the SSM provisions and our responses.

D. What other changes have been made to the NESHAP?

This rule also finalizes, as proposed, revisions to several other NESHAP requirements. To increase the ease and efficiency of data submittal and data accessibility, we are finalizing a requirement that owners and operators of facilities in the Solvent Extraction for Vegetable Oil Production source category submit electronic copies of initial notifications, initial startup reports, annual compliance certifications, deviation reports, and performance test reports through the EPA's CDX using the CEDRI. The initial notifications, initial startup reports, annual compliance certifications, deviation reports, and performance test reports are required to be submitted according to the deadlines specified in 40 CFR 63.2861. We also are finalizing, as proposed, provisions that allow

facility operators the ability to seek extensions for submitting electronic reports for circumstances beyond the control of the facility, *i.e.,* for a possible outage in the CDX or CEDRI or for a *force majeure* event in the time just prior to a report's due date, as well as the process to assert such a claim.

The EPA is finalizing several minor technical editorial changes to the rule. The EPA is finalizing several definitions in 40 CFR 63.2872 to harmonize with the removal of the SSM requirements and to clarify existing provisions. The definitions of ''Compliance ratio,'' ''Nonoperating period,'' ''Normal operating period,'' and ''Operating month'' are revised in the final rule to clarify that we have removed malfunction periods as a distinct source operating status during which no limits or work practices applied. The definition of ''Normal operating period'' is also revised to clarify that this definition also applies to ''normal operation.''

The EPA is revising the definition of ''Hazardous Air Pollutant (HAP)'' as proposed to remove the reference to the date of April 12, 2001. Finally, the EPA is adding a definition for ''Nonoperating month'' as proposed.

The EPA is finalizing minor revisions to 40 CFR 63.2840(a)(1) and (b)(1), 40 CFR 63.2853(a)(2), and 40 CFR 63.2855(a)(3) to remove text that is redundant with the definition of ''Operating month'' in 40 CFR 63.2872. Finally, the EPA is revising Table 1 of 40 CFR 63.2850 to correct a typographical error in row ''(a)'' for malfunction periods.

The legal rationale and detailed changes for these revisions are set forth in the proposed rule (see 84 FR 30830).

E. What are the effective and compliance dates of the standards?

The revisions to the MACT standards being promulgated in this action are effective on March 18, 2020.

Existing affected sources and affected sources that commenced construction or reconstruction on or before June 27, 2019, must comply with the amendments no later than 180 days after March 18, 2020. Affected sources that commence construction or reconstruction after June 27, 2019 must comply with all requirements of 40 CFR part 63, subpart GGGG, no later than the effective date of the final rule or upon startup, whichever is later. The EPA is finalizing three changes that would affect ongoing compliance requirements for the Solvent Extraction for Vegetable Oil Production NESHAP. First, for all sources, we are finalizing a requirement that initial notifications, initial startup reports, annual compliance certifications, deviation reports, and performance test results be electronically submitted. Next, the EPA is finalizing changing the requirements for SSM by removing the exemption from the requirements to meet the standard during SSM periods. For new or significantly modified sources, we are finalizing an option for facilities to follow new work practice standards for periods of initial startup. From our assessment of the timeframe needed for implementing the entirety of the revised requirements, the EPA proposed a period of 180 days to be the most expeditious compliance period practicable for existing affected sources or affected sources that commenced construction or reconstruction on or before June 27, 2019. No comments on the compliance period were received during the public comment period and the 180-day period is being finalized as proposed. Thus, the compliance date of the final amendments for all existing sources and new sources that commenced construction or reconstruction on or before June 27, 2019, will be September 15, 2020. The compliance date of the final amendments for new sources that commence construction or reconstruction after June 27, 2019, will be March 18, 2020.

IV. What is the rationale for our final decisions and amendments for the Solvent Extraction for Vegetable Oil Production source category?

For each issue, this section provides a description of what we proposed and what we are finalizing for the issue, the EPA's rationale for the final decisions and amendments, and a summary of key comments and responses. For all comments not discussed in this preamble, comment summaries, and the EPA's responses can be found in the comment summary and response document, *Summary of Public Comments and Responses for the Risk and Technology Review for Solvent Extraction For Vegetable Oil Production,* which is available in the docket for this rulemaking.

A. Residual Risk Review for the Solvent Extraction for Vegetable Oil Production Source Category

1. What did we propose pursuant to CAA section 112(f) for the Solvent Extraction for Vegetable Oil Production source category?

Pursuant to CAA section 112(f), the EPA conducted a residual risk review and presented the results of this review, along with our proposed decisions regarding risk acceptability and ample margin of safety, in the June 27, 2019, proposed rule for 40 CFR part 63, subpart GGGG (84 FR 30812). The results of the risk assessment for the proposal are presented briefly in Table 2 of this preamble. More detail may be found in the residual risk technical support document, *Residual Risk Assessment for the Solvent Extraction for Vegetable Oil Production Source Category in Support of the 2019 Risk and Technology Review Final Rule,* which is available in the docket for this rulemaking.

TABLE 2—SOLVENT EXTRACTION FOR VEGETABLE OIL PRODUCTION INHALATION PROPOSED RISK ASSESSMENT RESULTS

Number of facilities [1]	Maximum individual cancer risk (in 1 million) [2]	Estimated population at increased risk of cancer ≥1-in-1 million	Estimated annual cancer incidence (cases per year)	Maximum chronic noncancer TOSHI [3]	Maximum screening acute noncancer HQ
88	Based on Actual Emissions Level				
	<1	0	0.00005	0.7 (n-hexane)	HQ_{REL} = 0.7 (acrolein)
	Based on Allowable Emissions Level				
	<1	0	0.0002	2 (n-hexane)	N/A

[1] Number of facilities evaluated in the risk analysis.
[2] Maximum individual excess lifetime cancer risk due to HAP emissions from the source category.
[3] The target organ with the highest target organ-specific hazard index (TOSHI) for the Solvent Extraction for Vegetable Oil Production source category is the nervous system (neurocognitive and neurobehavioral effects).

The results of the proposed inhalation risk assessment using actual emissions data, as shown in Table 2 of this preamble, indicate the estimated cancer maximum individual risk (MIR) is less than 1-in-1 million. At proposal, the total estimated cancer incidence from this source category was estimated to be 0.00005 excess cancer cases per year, or 1 case every 20,000 years and for allowable emissions was 0.0002 excess cancer cases per year, or 1 case every 5,000 years driven by emissions of acetaldehyde and formaldehyde. At proposal, the maximum modeled chronic noncancer TOSHI for the source category based on actual emissions was estimated to be 0.7 and, for allowable emissions, was estimated to be 2 due to emissions of n-hexane. Approximately 13 people were estimated to have exposures resulting in a TOSHI greater than 1 if exposed to allowable emissions from this source category.

As shown in Table 2 of this preamble, the worst-case acute hazard quotient (HQ) (based on the reference exposure level (REL)) at proposal was less than 1 (0.7 based on the REL for acrolein). This value is the highest HQ that is outside facility boundaries. The multipathway risk screening assessment did not identify emissions of any HAP known to be persistent and bio-accumulative in the environment; therefore, no further evaluation of multipathway risk was conducted for this source category. Further, because we did not identify environmental HAP emissions, no quantitative environmental risk screening was conducted for this source category.

We conducted an assessment of facility-wide risks. The maximum lifetime individual cancer risk posed by the 88 facilities, based on facility-wide emissions at proposal, was 5-in-1 million with cadmium, nickel, arsenic, chromium (VI), and formaldehyde emissions from facility-wide external combustion boilers driving the risk. The maximum chronic noncancer TOSHI posed by facility-wide emissions was estimated to be 0.7 (for the nervous system) driven by source category n-hexane emissions.

We weighed all health risk factors, including those shown in Table 2 of this preamble, in our risk acceptability determination and proposed that the risks from the Solvent Extraction for Vegetable Oil Production source category are acceptable (section IV.C.1 of proposal preamble, 84 FR 30812, June 27, 2019).

We then considered whether the existing MACT standards for this source category provide an ample margin of safety to protect public health and whether, taking into consideration costs, energy, safety, and other relevant factors, standards are required to prevent an adverse environmental effect. In considering whether standards are required to provide an ample margin of safety to protect public health, we considered the same risk factors that we considered for our acceptability determination and also considered the costs, technological feasibility, and other relevant factors related to emissions control options that might reduce risk associated with emissions from the source category. We proposed that the current standards provide an ample margin of safety to protect public health and revision of the standards for the Solvent Extraction for Vegetable Oil Production source category are not required to provide an ample margin of safety to protect public health. We also proposed that it is not necessary to set a more stringent standard to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect (see section IV.B of proposal preamble, 84 FR 30812, June 27, 2019.)

2. How did the risk review change for the Solvent Extraction For Vegetable Oil Production source category?

We have not changed any aspect of the risk assessment since the June 27, 2019, RTR proposal for the Solvent Extraction for Vegetable Oil Production source category. We received several comments indicating that the risk assessment (1) Improperly included emissions of acetaldehyde that are not associated with the Solvent Extraction for Vegetable Oil Production source category, but are emitted from other facility processes; (2) overestimated actual emissions for certain facilities where the EPA assumed that reported volatile organic compound (VOC) emissions were n-hexane; and (3) overestimated allowable emissions for the source category based on the assumptions used to develop the MACT allowable-to-actual emissions multiplier.

As discussed in section IV.A.3 of this preamble, the inputs and assumptions in the risk assessment at proposal are likely to overestimate the risks from the Solvent Extraction for Vegetable Oil Production source category. However, the risks as modeled at proposal indicate that both the actual and allowable inhalation cancer risks to the individual most exposed are less than 1-in-1 million, well below the presumptive limit of acceptability of 100-in-1 million. The maximum chronic noncancer TOSHI due to inhalation exposures is less than 1 for actual emissions, and 2 for MACT-allowable emissions with an estimated 13 people exposed to a TOSHI greater than 1. Although for MACT-allowable emissions, the maximum chronic noncancer TOSHI due to inhalation exposures is 2, we note that due to the inherent health protective nature of our risk assessment methods and the uncertainties in this assessment (*i.e.,* the emissions dataset, dispersion modeling, and exposure estimates), our risk estimates are conservative. For example, risk estimates for allowable emissions were based on scaled-up actual emissions. At the first facility with a TOSHI value greater than 1, allowable emissions are based on permit data. At the other facility, allowable emissions are based on an allowable multiplier applied to actual emissions.

Additionally, the results of the acute screening analysis showed that acute risks were below a level of concern. Because the risk assessment already shows risks from the source category are acceptable and that the existing standards provide an ample margin of safety to protect public health, revision of the risk assessment to address the comments that our emission estimates were too high would not change the EPA's finding that the risks from the Solvent Extraction for Vegetable Oil Production source category are acceptable.

3. What key comments did we receive on the risk review, and what are our responses?

We received comments in support of and opposed to our proposed risk assessment and determination that no revisions to the standards are warranted under CAA section 112(f)(2) for the Solvent Extraction for Vegetable Oil Production source category. Generally, the comments that were not supportive of the acceptability and ample margin of safety determinations suggested changes to the underlying risk assessment methodology. The suggested changes to the EPA's risk assessment methodology included that the EPA should lower its presumptive limit of acceptability for cancer risks to below 100-in-1 million, include emissions outside of the source categories in question in the risk assessment, and assume that pollutants with noncancer health effects have no safe level of exposure. Other commenters asserted that the methodology for developing modeling inputs overestimated the actual or allowable emissions of certain pollutants from specific facilities, and subsequently overstated the risks from the source category. We evaluated all comments and determined that no

changes regarding our risk review were needed. These comments and our specific responses can be found below and in the comment summary and response document titled *Summary of Public Comments and Responses for the Risk and Technology Review for Solvent Extraction for Vegetable Oil Production,* which is available in the docket for this action.

Comment: One commenter stated that the acetaldehyde emissions that were modeled for the ADM-Clinton facility were not associated with the vegetable oil process and should not have been included in the source category modeling file. The commenter stated that the EPA should correct the risk assessment by removing acetaldehyde for the ADM-Clinton facility.

Response: As noted at proposal, we included acetaldehyde emissions in the modeling file for the source category with the understanding that their inclusion in the assessment would result in a conservative estimate of risk. We acknowledge that a reassessment of risk that excludes acetaldehyde emissions from the facility would result in lower facility emissions, and potentially lower the source category risks associated with acetaldehyde. Therefore, because revising the assessment by removing acetaldehyde emissions from the source category modeling file would not change the outcome of our risk determination, we are not undertaking further analysis. We note that the acetaldehyde emissions would continue to be considered as part of the facility-wide risk assessment (see 84 FR 30824) and whole facility risks.

Comment: One commenter stated that the EPA overestimated actual emissions for nine facilities where the EPA assumed that 100 percent of the reported VOC emissions were emitted as n-hexane. The commenter stated that although the EPA did not identify the nine facilities, the commenter's review indicated that actual emissions in the modeling file for several sources significantly exceeded the actual 2014 emissions of n-hexane. The commenter stated that the EPA should identify the extent to which the reported HI (0.7) may be affected by this assumption. The commenter also stated that the EPA overestimated the allowable-to-actual ratio used to estimate allowable emissions for multiple facilities. The commenter asserted that although the EPA did not identify the facilities that were used to estimate an allowable-to-actual ratio, they believe, based on a review of the data, that the EPA overestimated the allowable-to-actual ratio by incorrectly assuming that n-hexane emissions were equal to total solvent (VOC) loss or by not accounting for the volume fraction of n-hexane in solvent.

Response: As noted at proposal (84 FR 30818), the EPA assumed for certain facilities that all solvent loss reported as VOC is emitted as n-hexane. We adopted this approach where data for facility hexane emissions were unavailable or lacking, recognizing that this approach would provide the most conservative estimate of risk. Additionally, the MACT allowable emissions multiplier conservatively assumed that all loss of n-hexane in the solvent extraction process is emitted to the atmosphere (84 FR 30819). The proposed approach was adopted taking into consideration that the volume fraction of n-hexane may vary significantly within a solvent (the solvent used in vegetable oil production facilities is 100-percent VOC and may range from less than 1 percent to 88-percent n-hexane). Where emissions of n-hexane or the volume fraction of n-hexane were not readily available from permit materials, we conservatively assumed all solvent loss is n-hexane. Therefore, the risk assessment does likely overestimate the actual and allowable emissions for certain facilities; as noted at proposal, these conservative assumptions were adopted to account for the potential ''worst-case'' risks given that we lacked complete information on the n-hexane emissions for specific facilities. Although we acknowledge that the source category risks would be lower with the adjustments requested by the commenters, revision of the actual emissions or MACT-allowable emissions in the modeling file would not change the EPA's conclusions regarding risk.

Comment: One commenter objected to the EPA's methodology for the acute risk assessment. The commenter stated that the risk assessment is weakened because the EPA used ''reasonable worst-case'' conditions. The commenter stated that after recognizing the need to evaluate the worst-case set of conditions, it is inherently contradictory and circular for the EPA to decide to ignore the impacts by deciding that the worst-case is not actually ''reasonable.'' Another commenter stated the assessment of risks for acute exposure is conservative. It assumes that estimated 1-hour peak emissions occur at the same time as the ''reasonable worst-case'' meteorological conditions and that an individual will be exposed at this time and under these conditions at the location of the maximum predicted impact.

Response: The EPA disagrees that our Acute Screening-Level Assessment should not be based on ''reasonable worst-case'' meteorological conditions. In developing an acute exposure scenario, we estimate 1-hour exposure concentrations through air dispersion modeling during hours of peak emissions. However, hourly emissions data are not typically available, and the exact hours of peak emissions are often unknown, making it difficult to determine the meteorological conditions to model with the peak emissions. We make assumptions about when peak hourly emissions occur. In a worst-case scenario, peak hourly emissions would occur during the 1 hour of the year with the worst-case air dispersion conditions (*i.e.,* low, continuous wind speeds blowing in a specific direction). However, the probability of peak hourly emissions occurring in the same hour as the worst-case air dispersion conditions is extremely low. For example, as documented in Appendix 5 of the *Residual Risk Assessment for the Solvent Extraction for Vegetable Oil Production Source Category in Support of the 2019 Risk and Technology Review Final Rule,* available in the docket for this rulemaking, conservatively the probability of these two events occurring simultaneously is about 1-in-200,000 (or a 0.0005 percent chance). Instead, we use ''reasonable worst-case'' meteorological conditions. This approach strikes a balance of being health protective without overestimating acute exposures and has a reasonable probability of occurrence (conservatively, an 88-in-200,000 chance or 0.044 percent). Using the ''reasonable worst-case'' meteorological conditions, the scenario we modeled is a rare event (peak emissions would have a 0.044% chance of occuring during the same hour as the ''reasonable worst-case'' meteorology based on conservative assumptions, or a 99.956% chance of not occuring during that hour) rather than a scenario that is extremely unlikely (peak emissions would have a 0.0005% chance of occuring during the same hour as the worst-case meteorology, or a 99.9995% chance of not occuring during that hour).

After review of all the comments received, we determined that no changes to the risk assessment were necessary. The comments and our specific responses can be found in the document, *Summary of Public Comments and Responses for the Risk and Technology Review for the Solvent Extraction for Vegetable Oil Production Source Category,* available in the docket for this action.

4. What is the rationale for our final approach and final decisions for the risk review?

As noted in our proposal, the EPA sets standards under CAA section 112(f)(2) using ''a two-step standard-setting approach, with an analytical first step to determine an 'acceptable risk' that considers all health information, including risk estimation uncertainty, and includes a presumptive limit on MIR of ''approximately 1-in-10 thousand'' (see 54 FR 38045, September 14, 1989). We weigh all health risk factors in our risk acceptability determination, including the cancer MIR, cancer incidence, the maximum cancer TOSHI, the maximum acute noncancer HQ, the extent of noncancer risks, the distribution of cancer and noncancer risks in the exposed population, and the risk estimation uncertainties.

Since proposal, neither the risk assessment nor our determinations regarding risk acceptability, ample margin of safety, and adverse environmental effects have changed. For the reasons explained in the proposed rule, we determined that the risks from the Solvent Extraction for Vegetable Oil Production source category are acceptable, and the current standards provide an ample margin of safety to protect public health and prevent an adverse environmental effect. Therefore, we are not revising the standards for this source category pursuant to CAA section 112(f)(2) based on the residual risk review, and we are readopting the existing standards under CAA section 112(f)(2).

B. Technology Review for the Solvent Extraction for Vegetable Oil Production Source Category

1. What did we propose pursuant to CAA section 112(d)(6) for the Solvent Extraction for Vegetable Oil Production source category?

Pursuant to CAA section 112(d)(6), we proposed to conclude that no revisions to the current MACT standards for this source category are necessary for control of n-hexane emissions from vegetable oil production facilities (sections IV.C of proposal preamble, 84 FR 30825). We did not find any developments in practices, processes, and control technologies that could be applied to solvent extraction for vegetable oil process vents and that could be used to reduce emissions from solvent extraction for vegetable oil production facilities. We also did not identify any developments in work practices, pollution prevention techniques, or process changes that could achieve emission reductions from solvent extraction for vegetable oil process vents. We identified for consideration the use of a cryogenic condenser after the main vent as an add-on control option, based on a review of best available control technology analyses where such controls were previously considered. However, based on the costs and emission reductions for the proposed options, we did not find the use of a cryogenic condenser as cost effective for reducing emissions from these emission sources at solvent extraction for vegetable oil production units; and we proposed that it is not necessary to revise the MACT standards for these emission sources pursuant to CAA section 112(d)(6). Additional details of our technology review can be found in the memorandum, *CAA Section 112(d)(6) Technology Review for the Solvent Extraction for Vegetable Oil Production Source Category,* which is available in the docket for this action.

2. How did the technology review change for the Solvent Extraction for Vegetable Oil Production source category?

We have not changed any aspect of the technology review since the June 27, 2019, RTR proposal for the Solvent Extraction for Vegetable Oil Production source category.

3. What key comments did we receive on the technology review, and what are our responses?

We received comments in support of and opposed to the proposed determination from the technology review that no revisions were warranted under CAA section 112(d)(6). We evaluated the comments and determined that no changes regarding our determination were needed. These comments and our specific responses can be found in the comment summary and response document titled *Summary of Public Comments and Responses for the Risk and Technology Review for Solvent Extraction for Vegetable Oil Production,* which is available in the docket for this action.

4. What is the rationale for our final approach for the technology review?

We evaluated all of the comments on the EPA's technology review and determined that no changes to the review are needed. For the reasons explained in the proposed rule, we determined that no cost-effective developments in practices, processes, or control technologies were identified in our technology review to warrant revisions to the standards. More information concerning our technology review, and how we evaluate cost effectiveness, can be found in the memorandum titled *CAA Section 112(d)(6) Technology Review for the Solvent Extraction for Vegetable Oil Production Source Category,* which is available in the docket for this action, and in the preamble to the proposed rule (84 FR 30825). Therefore, pursuant to CAA section 112(d)(6), we are finalizing our technology review as proposed.

C. SSM for the Solvent Extraction for Vegetable Oil Production Source Category

1. What amendments did we propose to address emissions during periods of SSM?

We proposed removing and revising provisions related to SSM that are not consistent with the requirement that standards apply at all times. We proposed that the emission standards for normal operation apply at all times, except for periods of initial startup, for new or significantly modified sources as described below. We proposed alternate standards for initial startup periods for new or significantly modified sources. Specifically, we proposed that new or significantly modified facilities operating in an initial startup period would operate the mineral oil absorption system and solvent condensers at all times during the initial startup period. We also proposed that facilities establish and follow site-specific operating ranges for temperature and vacuum for the desolventizing and oil distillation units associated with solvent recovery. New and significantly modified facilities would also continue to have the option to meet the requirements for normal operating periods in Table 1 of 40 CFR 63.2850, in lieu of the work practice standards. We also proposed to revise the definition of ''Initial startup period'' to clarify the time at which an initial startup period ends and a normal operating period begins.

We proposed to remove malfunction periods as a distinct source operating status, which previously allowed sources to exclude data collected during the ''malfunction period'' when determining compliance with the emission standards. Under the proposed rule, sources that experience an unscheduled shutdown as a result of a malfunction, continue to operate during a malfunction (including the period reasonably necessary to correct the malfunction), or start up after a shutdown resulting from a malfunction must instead meet the emission standard requirements for either a

normal operating period or the work practice standards for an initial startup period (if applicable) in 40 CFR 63.2850 and Table 1 of 40 CFR 63.2850. We also proposed to remove reference to SSM exemptions from the general duty requirements,[3] to remove SSM plans, to remove references to SSM exemptions in requirements related to compliance with the standards and performance testing, and to revise recordkeeping and reporting requirements that are not consistent with the requirement that standards apply at all times. More information concerning our proposal on SSM can be found in the proposed rule (84 FR 30825, June 27, 2019).

2. How did the SSM provisions change since proposal?

We are finalizing the SSM provisions as proposed, except for minor clarifications. We are finalizing the proposed alternate work practice standards for initial startup periods for new or significantly modified sources, and we are finalizing our proposal to remove malfunction periods as a source operating status, which previously allowed sources to exclude data collected during the ''malfunction period'' when calculating their compliance ratio according to 40 CFR 63.2840. We are finalizing the removal and revision of SSM requirements related to general duty, SSM plans, compliance with the standards, and performance testing as proposed (84 FR 30825). We are revising the recordkeeping requirements at 40 CFR 63.2862 and the reporting requirements at 40 CFR 63.2861 as proposed, with the exception of minor revisions to clarify how to designate the date a deviation occurred and the duration of the deviation. For deviations from the compliance ratio for facilities operating under a normal operating period, the date of the deviation is the date the compliance ratio determination is made, and the duration of the deviation is the length of time taken to address the cause of the deviation (including the duration of any malfunction) and to return the affected unit(s) to its normal or usual manner of operation. For deviations from the work practice standard for facilities operating under an initial startup period, the date of the deviation is the date when the facility fails to comply with any of the work practice standards in 40 CFR 63.2840(h), and the duration of the deviation is the length of time taken to return to the work practice standards. We have also removed the requirement to record and report the time of day the deviation occurred, since deviations from the compliance ratio are determined at the end of the period.

3. What key comments did we receive on the SSM revisions and what are our responses?

We received one comment supporting our proposed removal of the exemption in the regulations for emissions during SSM periods. We received two comments supporting our proposal to establish an option to follow a work practice standard during initial startup periods for new or significantly modified sources, and did not receive any comments opposing the proposed work practice standards during initial startup periods. We received additional comments requesting that startup or shutdown periods be taken into account when setting the MACT standard. We received comments both for and against the proposed removal of ''malfunction periods'' as a distinct source operating status. We also received comments requesting clarification on the recordkeeping and reporting requirements for the date, time, and duration of a deviation. We evaluated all comments and determined that no changes to the proposed alternate work practice standards for initial startup periods for new or significantly modified sources; no changes to the proposed removal of requirements that allowed sources to designate the operating status as a distinct ''malfunction periods'' (facilities must instead meet the requirements of normal operation or initial startup); and no changes to the proposed removal or revision of provisions related to SSM are required, with the exception of minor clarifications as discussed in this section.

Comment: Two commenters stated that the EPA should take periods of startup and shutdown into account when setting the MACT emissions standards. The commenters stated that if the EPA is removing the exemption of startup and shutdown emissions from the calculation of the compliance ratio, the EPA should recalculate the MACT emission limits based on normal operation plus periods of startup and shutdown. The commenters stated that the EPA has indicated the current NESHAP provides an ample margin of safety to protect public health, and that this indicates there is ample room to increase the MACT limits to more appropriate levels that include the startup and shutdown operations. Another commenter stated that the proposed elimination of relief for SSM events is not required for the rule to be consistent with *Sierra Club* v. *EPA.* The commenter asserted that other court opinions have emphasized the need for standards to accommodate higher emission levels that occur at times other than normal operations.

Response: We do not agree that the MACT emission limits should be recalculated to include periods of startup and shutdown. We disagree with the commenter's suggestion that the legal precedent established in case law (*i.e., Sierra Club* v. *EPA,* 551 F.3d 1019 (D.C. Cir. 2008)) is not relevant. The *Sierra Club* decision held that emissions limitations under CAA section 112 must apply continuously and meet minimum stringency requirements, even during periods of SSM. Consistent with *Sierra Club* v. *EPA,* for the reasons explained in the proposal preamble at 83 FR 30285, we are finalizing our proposal to eliminate the SSM language in 40 CFR part 63, subpart GGGG. Subpart GGGG had both rule-specific SSM language and references to SSM language in the part 63 General Provisions in Table 1 of 63.2870, specifically reference to 40 CFR 63.6(f)(1). As we explained in the proposal, our SSM-related rule revisions are in response to the *Sierra Club* Court's vacatur of the SSM exemption in 40 CFR 63.6(f)(1) and 40 CFR 63.6(h)(1). When incorporated into CAA section 112(d) regulations for specific source categories, these two provisions exempted sources from the requirement to comply with otherwise applicable MACT standards during periods of SSM. The Court's vacatur rendered those provisions null and void prior to this rulemaking. The mandate implementing the Court's decision was issued on October 16, 2009, at which time the vacated SSM provision 40 CFR 63.6(f)(1) referenced by subpart GGGG was no longer in effect. Eliminating reference to this provision, and other related General Provisions referenced in subpart GGGG, is a ministerial action by the EPA to reflect the vacatur by the Court. We also eliminated the rule-specific SSM provisions in subpart GGGG. The final standards will apply at all times, consistent with the *Sierra Club* decision.

As an alternative approach consistent with *Sierra Club,* the EPA may designate different standards to apply during startup and shutdown (as noted in the proposal, the EPA is not obligated to set standards for periods of malfunction). For this category, the compliance approaches required by state regulatory authorities led us to decide special startup/shutdown standards were unnecessary for existing sources. Based

[3] We proposed to add general duty regulatory text at 40 CFR 63.2840(g) to reflect the general duty to minimize emissions, while eliminating the reference to periods covered by an SSM exemption (see 84 FR 30828).

on discussions with industry, there are not significant differences in the production process or operation of solvent recovery equipment during startup or shutdown of an existing facility that would preclude the facility from complying with the existing standards. A review of title V permits identified that approximately 35 percent of existing facilities are already required to account for periods of routine startup (not initial startup) and shutdown in determining their compliance ratio. This requirement was found commonly across states and regions, indicating that existing sources operating during periods of routine startup and shutdown are able to demonstrate compliance with the emission standards. Furthermore, the commenter did not provide any evidence that emissions during routine startup and shutdown vary considerably from normal operation. Consequently, the final rule's elimination of periods of startup and shutdown for existing sources reflects this capability.

For the reasons explained in the proposal preamble, we are finalizing alternate standards for periods of initial startup for new or significantly modified sources. Because the initial startup period reflects a non-steady state of production, emissions testing during this period would not likely be representative or yield meaningful results for the establishment of separate emission limits. As discussed at proposal, control of n-hexane emissions at vegetable oil production facilities is accomplished through solvent recovery and is based on inter-related process equipment that is often custom built to the specific configuration and needs of the plant. During an initial startup period, facility equipment is tested, added, or replaced as the facility gradually increases production, and emissions during this period may reflect variability that is not generally reflective of normal or steady-state operations. New and modified equipment is often brought online in a phased approach, and each phase can necessitate adjustments in both new and existing equipment in the process in order to identify and correct problems, such as equipment that is not operating as designed and that requires repair or replacement. The EPA evaluated the available data for new or significantly modified sources to establish potential standards for periods of initial startup, including review of operating permits from various state and local agencies and EPA Regional offices. We noted that the standards have not previously required—and state, local, and Regional offices have not collected—emissions data for these facilities during their initial startup periods. Further, where the EPA identified a recently constructed facility with permitted MACT allowable solvent loss for an initial startup period, we determined that the allowable solvent loss for the facility was not based on measured data, and would not be representative of initial startup periods for other facilities in the source category. Although we requested information on emissions and the operation of processes during initial startup periods, we did not receive sufficient information, including additional quantitative emissions data, on which to base a numeric standard for initial startup periods at new or significantly modified facilities. The EPA recognizes that the initial startup period, which is a one-time event for new sources and an infrequent event for significantly modified sources, is not a typical startup period that may occur as part of routine or seasonal startups of a plant. Instead, the initial startup period includes evaluation and replacement of new equipment as each phase is brought online and production is gradually increased. Therefore, emissions testing during initial startup would be both economically and technically infeasible. Consequently, the EPA is finalizing a work practice standard rather than an emissions limit for this period.

Notwithstanding the finding that the MACT-based limits of the initial NESHAP provide and ample margin of safety, the EPA lacks the authority to relax limits developed in the MACT process based on finding that the limits provide an ample margin of safety. Were the EPA to do so, then the limits would not meet the strict structure of MACT. The risk-based limits under CAA section 112(f)(2) were intended to augment MACT when the post-MACT risks did not provide an ample margin of safety to protect public health. There is no indication in the statute that the risk-based standards were intended to revoke the requirements to have MACT standards. A risk-based standard is only required when the MACT-based does not sufficiently reduce risk (see CAA section 112(f)(2)(A)).

Additionally, the EPA's finding is that the existing MACT-based standard does not need to be made more stringent to comply with CAA section 112(f)(2) (*i.e.,* to provide an ample margin of safety). The EPA has not made a finding that the existing standards somehow exceed an ample margin of safety. There is no finding that there is ''room to increase'' the limits while also complying with the requirement to provide an ample margin of safety required by CAA section 112(f)(2).

Comment: One commenter asserted that it would be arbitrary and capricious for the EPA to ignore the existence of malfunctions even at best-performing sources, or to assume that the best-performing sources achieve emission levels that they do not achieve part of the time. The commenter urged that if the EPA adopts MACT standards that it recognizes even the best-performing existing sources cannot achieve part of the time, the EPA would be going beyond the MACT floor. Three commenters stated that the EPA should take malfunctions into account when adopting emissions standards. One commenter stated that it is not apparent from the proposed rule why the EPA believes it needs to remove the current provisions related to malfunctions. The commenter asserted that the EPA cannot change its position and withdraw a previously promulgated provision without providing a full explanation of the reason(s) for the change. The same commenter recommended that the EPA could instead establish numerical emission limitations that have an averaging time of sufficient duration that short, infrequent spikes in emissions due to malfunctions would not cause the source to exceed the emission limitation. Alternatively, the commenter recommended that the EPA could promulgate design, equipment, work practice, or operational standards in lieu of a numerical standard. Two commenters stated that the EPA should maintain an option in 40 CFR 63.2850(e)(2) either to meet the requirements applicable to normal operating periods or to meet the requirements for malfunction periods. These commenters urged that otherwise there could be unavoidable exceedances of the standards. The two commenters recommended that the EPA could adopt similar work practice standards for malfunction periods as proposed for initial startup periods. Another commenter suggested work practices such as monitoring of operating parameters to identify a malfunction and stopping or cutting back the process. One commenter supported the removal of the malfunction exemptions, stating there is no lawful or rational justification for creating non-numerical work practice standards during malfunctions.

Response: We disagree with the commenters' assertions that we must set revised or separate standards for periods of malfunction. As discussed in the preamble to the proposed rule, as the Court recognized in *U.S. Sugar Corp,* accounting for malfunctions in setting standards would be difficult, if not

impossible, given the myriad different types of malfunctions that can occur across all sources in the category and given the difficulties associated with predicting or accounting for the frequency, degree, and duration of various malfunctions that might occur. Id. at 608 (''the EPA would have to conceive of a standard that could apply equally to the wide range of possible [ ] malfunctions, ranging from an explosion to minor mechanical defects. Any possible standard is likely to be hopelessly generic to govern such a wide array of circumstances.''). As such, the performance of units that are malfunctioning is not ''reasonably'' foreseeable. See, *e.g., Sierra Club* v. *EPA,* 167 F.3d 658, 662 (D.C. Cir. 1999) (''The EPA typically has wide latitude in determining the extent of data-gathering necessary to solve a problem. We generally defer to an agency's decision to proceed on the basis of imperfect scientific information, rather than to 'invest the resources to conduct the perfect study.'''). See also, *Weyerhaeuser* v. *Costle,* 590 F.2d 1011, 1058 (D.C. Cir. 1978) (''In the nature of things, no general limit, individual permit, or even any upset provision can anticipate all upset situations. After a certain point, the transgression of regulatory limits caused by 'uncontrollable acts of third parties,' such as strikes, sabotage, operator intoxication or insanity, and a variety of other eventualities, must be a matter for the administrative exercise of case-by-case enforcement discretion, not for specification in advance by regulation.''). In addition, emissions during a malfunction event can be significantly higher than emissions at any other time of source operation. For example, if an air pollution control device with 99-percent removal goes off-line as a result of a malfunction (as might happen if, for example, the bags in a baghouse catch fire) and the emission unit is a steady state type unit that would take days to shut down, the source would go from 99-percent control to zero control until the control device was repaired. The source's emissions during the malfunction would be 100 times higher than during normal operations. As such, the emissions over a 4-day malfunction period would exceed the annual emissions of the source during normal operations. As this example illustrates, accounting for malfunctions could lead to standards that are not reflective of (and significantly less stringent than) levels that are achieved by a well-performing non-malfunctioning source. It is reasonable to interpret CAA section 112 to avoid such a result. The EPA's approach to malfunctions is consistent with CAA section 112 and is a reasonable interpretation of the statute.

As noted at proposal, the EPA considers whether circumstances warrant setting standards for a particular type of malfunction and, if so, whether the EPA has sufficient information to identify the relevant best performing sources and establish a standard for such malfunctions. The EPA has also considered the need for a work practice for periods of malfunction for vegetable oil production facilities. Although we requested information on emissions and the operation of processes during malfunction periods in our consultations with state agencies and industry, we did not receive sufficient information for development of proposed standards. Therefore, as part of the proposal, the EPA solicited information on the type of events that constitute a malfunction event, industry best practices, and the best level of emission control during malfunction events. The EPA also requested commenters provide information on the costs associated with any recommended work practices. In addition, the EPA solicited specific supporting data on HAP emissions during malfunction events, including the cause of malfunction, the frequency of malfunction, duration of malfunction, and the estimate of HAP emitted during each malfunction. In this case, although we requested comment and information to support the development of a standard during periods of malfunction, we did not receive sufficient information, including additional quantitative emissions data, on which to base a standard. Absent sufficient information, it is not reasonable at this time to establish a work practice standard for periods of malfunction for this source category. For these reasons, we are not setting separate standards for periods of malfunction. Under the final rule, sources that experience an unscheduled shutdown as a result of a malfunction, continue to operate during a malfunction (including the period reasonably necessary to correct the malfunction), or start up after a shutdown resulting from a malfunction must instead meet the emission standard requirements for either a normal operating period or the work practice standards for an initial startup period (if a new or significantly modified source) in 40 CFR 63.2850 and Table 1 of 40 CFR 63.2850. We note that sources must still meet the general duty requirements in 40 CFR 63.2840(g) and should address malfunctions expeditiously in order to maintain any affected source, including associated air pollution control equipment and monitoring equipment, and minimize emissions.

Nevertheless, the EPA acknowledges that including solvent loss from a one-time event (like a malfunction) in the 12-month compliance ratio could cause a deviation for one or more monthly compliance ratio determinations, and would remain in the rolling compliance determination for up to 1 year (12 months). We also recognize that it is possible that a malfunction that causes a 12-month compliance ratio to be exceeded might have been corrected well before the first full 12-months have passed. Although a facility would need to retain records of any deviation and the corrective action(s) performed, no additional corrective action would be required at the time the 12-month compliance ratio is officially exceeded in subsequent months if the facility demonstrates the exceedance is from a prior malfunction that has been corrected. Facilities would be able to provide such an explanation in their deviation reports; specifically, we have revised the deviation reporting requirements in the final rule to include a requirement that facilities flag and provide an explanation for any deviation from the compliance ratio for which a deviation report is being submitted for more than 1 consecutive month (*i.e.,* include a reference to the original date and reporting of the deviation) (see 40 CFR 63.2861(b)). Further, as discussed below in this section, we have clarified that the duration of the deviation from the compliance ratio is the length of time taken to address the cause of the deviation (including the duration of any malfunction) and to return the affected unit(s) to its normal or usual manner of operation. Therefore, facilities must retain records of the date and duration of the malfunction, as well as the corrective action(s) performed, to demonstrate the basis for the deviation in subsequent periods.

As further explained at proposal, ''[i]n the event that a source fails to comply with the applicable CAA section 112(d) standards as a result of a malfunction event, the EPA would determine an appropriate response based on, among other things, the good faith efforts of the source to minimize emissions during malfunction periods, including preventive and corrective actions, as well as root cause analyses to ascertain and rectify excess emissions. The EPA would also consider whether the source's failure to comply with the CAA section 112(d) standard was, in fact,

sudden, infrequent, not reasonably preventable and was not instead caused in part by poor maintenance or careless operation. 40 CFR 63.2 (definition of malfunction). If the EPA determines in a particular case that an enforcement action against a source for violation of an emission standard is warranted, the source can raise any and all defenses in that enforcement action and the federal district court will determine what, if any, relief is appropriate. The same is true for citizen enforcement actions. Similarly, the presiding officer in an administrative proceeding can consider any defense raised and determine whether administrative penalties are appropriate'' (84 FR 30828).

Comment: We received one comment requesting clarification on the revised reporting and recordkeeping requirements for deviations. The commenter requested that the EPA clarify how a facility should designate the date a deviation occurred. The commenter recommended that because there is a single compliance ratio determination for an operating month, the rule should specify that a deviation be reported as occurring on the date the compliance ratio determination is made. The commenter also requested clarification on the duration of a deviation, noting that solvent loss from a one-time event (like a malfunction) could cause a deviation for one or more monthly compliance ratio determinations. The commenter stated it is unreasonable to require facilities to report events that may last only 1 day as having a duration of 30 days or even longer, and asked the EPA to clarify if the deviation reporting requirements only apply to work practice standards. Finally, the commenter stated the reporting template should not require facilities to report the time of a deviation; the commenter urged that the time of day a deviation occurs is not needed to determine compliance with the standards.

Response: We agree with the commenter and have revised the reporting and recordkeeping requirements for deviations for clarification. Specifically, we have revised the recordkeeping requirements of 40 CFR 63.2862(g)(1) to clarify that for deviations from the compliance ratio, the date of the deviation is the date the compliance ratio determination is made. For deviations from the work practice standard during the initial startup period, the date of the deviation is the date when the facility fails to comply with any of the work practice standard in 40 CFR 63.2840(h) (*e.g.,* if the facility fails to operate the mineral oil absorption system or the solvent condenser at all times during the initial startup period, or fails to meet the site-specific operating limits established by the facility). These dates must be reported in the deviation notification report according to the final rule requirements at 40 CFR 63.2861(b)(5). We have revised 40 CFR 63.2862(g)(1) to clarify that for deviations from the compliance ratio, the duration of the deviation is the length of time taken to address the cause of the deviation (including the duration of any malfunction) and to return the affected unit(s) to its normal or usual manner of operation. For deviations from the work practice standard during the initial startup period, the duration of the deviation is the length of time taken to return to the work practice standards. The final rule requirements are consistent with the prior requirements of 40 CFR 63.10(b)(2)(ii) to retain a record of the ''occurrence and duration of each malfunction'' and are necessary to allow the EPA to determine the severity of any failure to meet a standard. Finally, we have revised the final rule requirements to remove the requirement to record or report the time of a deviation, as this information is not necessary to determine compliance with the standard.

Additional comments on the SSM provisions and our specific responses to those comments can be found in the document titled *Summary of Public Comments and Responses for the Risk and Technology Review for Solvent Extraction for Vegetable Oil Production,* which is available in the docket for this action.

4. What is the rationale for our final approach and final decisions to address emissions during periods of SSM?

We evaluated all the comments on the EPA's proposed amendments to the SSM provisions. For the reasons explained in the proposed rule (84 FR 30812), we determined that these amendments appropriately remove and revise provisions related to SSM that are not consistent with the requirement that the standards apply at all times. Therefore, we are finalizing the amendments to remove and revise provisions related to SSM, as proposed, with the exception of the clarifications discussed in this section.

D. Technical Amendments to the MACT Standards for the Solvent Extraction for Vegetable Oil Production Source Category

1. What other amendments did we propose for the Solvent Extraction for Vegetable Oil Production source category?

We proposed that owners and operators submit electronic copies of initial notifications, initial startup reports, annual compliance certifications, deviation reports, and performance test reports through the EPA's CDX using the CEDRI. For initial notifications, initial startup reports, annual compliance certifications, and deviation reports, the proposed rule requires that owners and operators use the appropriate spreadsheet template to submit information to CEDRI. We also proposed two broad circumstances in which we may provide extension to these requirements. We proposed at 40 CFR 63.2862(f) that an extension may be warranted due to outages of the EPA's CDX or CEDRI that precludes an owner or operator from accessing the system and submitting required reports. We also proposed at 40 CFR 63.2862(g) that an extension may be warranted due to a *force majeure* event, such as an act of nature, act of war or terrorism, or equipment failure or safety hazards beyond the control of the facility.

We proposed revisions to several definitions in 40 CFR 63.2872 to harmonize with the proposed removal of the SSM requirements and to clarify existing provisions, include revisions to definitions of ''Compliance ratio,'' ''Nonoperating period,'' ''Normal operating period,'' and ''Operating month'' to clarify where the malfunction period is excluded, and to the definition of ''Normal operating period'' to clarify that this definition also applies to ''normal operation.'' We also proposed to add a definition for ''Nonoperating month.'' We proposed to revise the definition of ''Hazardous air pollutant (HAP)'' to remove the reference to the date of April 12, 2001.

We proposed minor revisions to 40 CFR 63.2840(a)(1) and (b)(1), 40 CFR 63.2853(a)(2), and 40 CFR 63.2855(a)(3) to remove text that is redundant with the definition of ''Operating month'' in 40 CFR 63.2872. We also proposed a minor correction to Table 1 of 63.2850 to correct a typographical error in row ''(a)'' for malfunction periods.

2. How did the other amendments for the Solvent Extraction for Vegetable Oil Production source category change since proposal?

There are no changes to the proposed requirements for owners and operators to submit electronic copies of initial notifications, initial startup reports, annual compliance certifications, deviation reports, and performance test reports electronically. We also are finalizing, as proposed, the provisions that allow facility operators the ability to seek extensions for submitting electronic reports for circumstances beyond the control of the facility. There are no changes to the proposed definitions in 40 CFR 63.2872, or the minor revisions to 40 CFR 63.2840(a)(1) and (b)(1), 40 CFR 63.2853(a)(2), 40 CFR 63.2855(a)(3), or Table 1 of 40 CFR 63.2850.

3. What key comments did we receive on the other amendments for the Solvent Extraction for Vegetable Oil Production source category and what are our responses?

We received one comment providing input on the proposed requirement for owners and operators of vegetable oil production facilities to submit electronic copies of initial notifications, initial startup reports, annual compliance certifications, deviation reports, and performance test reports. The commenter stated that the EPA may not lawfully or rationally finalize ''exemption provisions'' based on CEDRI outages or ''*force majeure* events.'' The commenter stated the provisions do not set a firm deadline to request an extension of the reporting deadline. No commenters provided significant comments on the proposed definitions in 40 CFR 63.2872, or the proposed minor revisions to 40 CFR 63.2840(a)(1) and (b)(1), 40 CFR 63.2853(a)(2), 40 CFR 63.2855(a)(3), or Table 1 of 40 CFR 63.2850.

Comment: One commenter stated that the EPA must not finalize the proposed electronic reporting extension provisions because the definition of a force majeure event is too broad, the provisions do not set a firm deadline to request an extension of the reporting deadline, and the decision to allow an extension is solely within the discretion of the Administrator. The commenter urged that the proposed provisions are unlawful and arbitrary because they would create a broad and vague mechanism that a facility owner or operator could use to evade binding emission standards, by evading the binding compliance reporting deadlines set to assure compliance with those standards. The commenter further stated that the EPA should not import the concept of ''force majeure'' into any part of the CAA, as to do so is a variation of the prior malfunction exemptions that are unlawful under the CAA. The commenter also noted that the EPA has provided that there are no known issues with submission of ERT-formatted performance test and evaluation reports in CEDRI (per the Petroleum Refinery NESHAP), thus, there is no rational basis for providing the proposing reporting extensions. At a minimum, the commenter requested that the EPA set a new firm deadline to assure that the extension request allows only a temporary period when the facility need not report, such as a 10-day extension, rather than an open-ended extension without a deadline.

Response: The commenter states that the brief case-by-case extension of report submittal deadlines is a ''reporting exemption.'' This is not the case. The proposed provisions the commenter questions are in paragraphs 40 CFR 63.2861(h) and (i).

There is no exception or exemption to reporting, much less an exemption from compliance with the numerical emission standards, only a method for requesting an extension of the reporting deadline. Reporters are required to justify their request and identify a reporting date. There is no predetermined timeframe for the length of extension that can be granted, as this is something best determined by the Administrator (*i.e.,* the EPA Administrator or delegated authority as defined in 40 CFR 63.2) when reviewing the circumstances surrounding the request. Different circumstances may require a different length of extension for electronic reporting. For example, a tropical storm may delay electronic reporting for a day, but a Hurricane Katrina scale event may delay electronic reporting much longer, especially if the facility has no power, and as such, the owner or operator has no ability to access electronically stored data or to submit reports electronically. The Administrator will be the most knowledgeable of the events leading to the request for extension and will assess whether an extension is appropriate, and if so, a reasonable length for the extension. The Administrator may even request that the report be sent in hardcopy until electronic reporting can be resumed. While no new fixed duration deadline is set, the regulation requires that the report be submitted electronically as soon as possible after the CEDRI outage or after the force majeure event resolves.

The concept of force majeure has been implemented by the EPA in this context since May 2007 within the CAA requirements through the performance test extensions provided in 40 CFR 63.7(a)(4) and 60.8(a)(1). Like the performance test extensions, the approval of a requested extension of an electronic reporting deadline is at the discretion of the Administrator.

The EPA disagrees that the ability to request a reporting extension ''would create a broad and vague mechanism'' that owners and operators ''could use to evade binding emissions standards'' or evade ''binding compliance reporting deadlines'' for emissions standards. While reporting is an important mechanism for the EPA and air agencies to assess whether owners and operators are in compliance with emissions standards, reporting obligations are separate from (*i.e.,* in addition to) requirements that an owner or operator be in compliance with an emissions standard, especially where the deadline for meeting the standard has already passed and the owner or operator has certified and is monitoring operations to show that they are in compliance with the standard. The commenter references deadlines set forth in the CAA for demonstrating initial compliance following the effective date of emission standards, which differs from deadlines for submitting reports. There are no such deadlines stated in the CAA for report due dates, meaning the EPA has discretion to establish reporting schedules, and also discretion to allow a mechanism for extension of those schedules on a case-by-case basis. In fact, under the commenter's reasoning, if the statutory deadlines for compliance with standards were read to strictly apply to continuing reporting requirements, no such reporting could be required after 3 years from the promulgation of the standards. This would not be a reasonable result. Reporting deadlines are often different from compliance deadlines. Rules under 40 CFR part 60 and 63 typically allow months following an initial compliance deadline to conduct testing and submit reports, but compliance with standards is required upon the compliance date.

Additionally, the ability to request a reporting extension does not apply to a broad category of circumstances; on the contrary, the scope for submitting an extension request for an electronic report is very limited in that claims can only be made for an event outside of the owner's or operator's control that occurs in the five business days prior to the reporting deadline. The claim must then be approved by the Administrator, and in approving such a claim, the

Administrator agrees that something outside the control of the owner or operator prevented the owner or operator from meeting its reporting obligation. In no circumstance does this electronic reporting extension allow for the owner or operator to be out of compliance with the underlying emissions standards. If the Administrator determines that a facility has not acted in good faith to reasonably report in a timely manner, the Administrator can reject the claim and find that the failure to report timely is a deviation from the regulation. CEDRI system outages are infrequent, but the EPA knows when they occur and whether a facility's claim is legitimate. Force majeure events (*e.g.,* natural disasters impacting a facility) are also usually well-known events.

Finally, EPA disagrees that the existing statistics on the use of CEDRI and e-reporting precludes the need for a provision to account for an outage of the CEDRI system. Prudent management of electronic data systems builds in allowances for unexpected, non-routine delays, such as occurred on July 1, 2016 and October 20–23, 2017, and is consistent with the already-existing provisions afforded for unexpected, non-routine delays in performance testing [see 40 CFR 60.8(a)(1) and (2) and 40 CFR 63.7(a)(4)]. For both electronic reporting and performance testing, owners or operators are to conduct and complete their activities within a short window of time; the EPA believes it is prudent to allow owners or operators to make force majeure claims for situations beyond their reasonable control. The EPA also disagrees that incidental issues with questions on completing the form or the procedures for accessing CEDRI for which the CEDRI Helpdesk is available, are conditions that would be considered either force majeure or a CEDRI system outage. The existence of the Helpdesk for answering questions on procedures in submitting reports to CEDRI have no impact on the availability of CEDRI in such a circumstance. The purpose of these requests for extensions are to accommodate owners and operators in cases where they cannot successfully submit a report electronically for reasons that are beyond their control and occur during a short window of time prior to the reporting deadline. The extension is not automatic, and the Administrator retains the right to accept or reject the request. The language was added as part of the standard electronic reporting language based on numerous comments received on the proposal for the Electronic Reporting and Recordkeeping Requirements for the New Source Performance Standards (80 FR 15100). As such, we have determined that no changes to the electronic reporting requirements are necessary in the final rule.

Additional comments on the proposed electronic reporting requirements and other amendments and our specific responses to those comments can be found in the memorandum titled *Summary of Public Comments and Responses for the Risk and Technology Review for Solvent Extraction for Vegetable Oil Production,* available in the docket for this action.

4. What is the rationale for our final approach and final decisions for the other amendments for the Solvent Extraction for Vegetable Oil Production source category?

We evaluated the comment on the EPA's proposed amendments to require electronic reporting initial notifications, initial startup reports, annual compliance certifications, deviation reports, and performance test reports. For the reasons explained in the proposed rule, we determined that these amendments increase the ease and efficiency of data submittal and improve data accessibility. More information concerning the proposed requirement for owners and operators of vegetable oil production facilities to submit electronic copies of certain notifications and reports is in the preamble to the proposed rule (84 FR 30830, June 27, 2019) and the document, *Summary of Public Comments and Responses for the Risk and Technology Review for the Solvent Extraction for Vegetable Oil Production,* available in the docket for this action. Therefore, we are finalizing our approach for submission of initial notifications, initial startup reports, annual compliance certifications, deviation reports, and performance test reports as proposed.

V. Summary of Cost, Environmental, and Economic Impacts and Additional Analyses Conducted

A. What are the affected facilities?

The EPA estimates that there are 89 vegetable oil production facilities that are currently subject to the Solvent Extraction for Vegetable Oil Production NESHAP and would be affected by the final amendments. The basis of our estimate of affected facilities is provided in the memorandum, *Residual Risk Modeling File Documentation for the Solvent Extraction for Vegetable Oil Production Source Category,* which is available in the docket for this action. We additionally anticipate one new source per year. The EPA received comment on the proposed rule that some larger facilities may have significant modifications about once a year, therefore, we assume that eight existing vegetable oil production facilities may have a significant modification that could meet the revised requirements for initial startup periods.

B. What are the air quality impacts?

The EPA estimates that annual HAP emissions from the vegetable oil production facilities that are subject to the NESHAP are approximately 13,500 tpy.[4] Because the EPA is not revising the emission limits, we do not anticipate any quantifiable air quality impacts as a result of these amendments. However, we anticipate that the final requirements, including the work practice standards for the optional initial startup period, are at least as stringent as the current rule requirements. The work practice standards include requirements for facilities to operate controls, including the mineral oil absorption system and solvent condensers, at all times during the initial startup period. Facilities must also establish and follow site-specific operating ranges for temperature and vacuum for the desolventizing and oil distillation units associated with solvent recovery. We anticipate these requirements will minimize emissions during these periods.

C. What are the cost impacts?

The 89 vegetable oil production facilities that would be subject to the final amendments, and one additional new source per year, would incur minimal net costs to meet revised recordkeeping and reporting requirements, some estimated to have costs and some estimated to have cost savings. Nationwide costs associated with the final requirements are estimated to total $93,100 over the 3 years following promulgation of amendments (or $31,033 per year). The EPA believes that the vegetable oil production facilities that are known to be subject to the NESHAP can meet the final requirements without incurring additional capital or operational costs. Therefore, the only costs associated with the final amendments include a one-time burden for reviewing requirements of the amended rule, and a one-time burden associated with recordkeeping and reporting labor costs for initial startup periods for new, reconstructed, or significantly modified

[4] The annual HAP emission estimates include emissions from 88 facilities. Annual emissions are not yet available for one newly constructed facility.

facilities. The EPA assumed in the proposed rule that one potential new or reconstructed vegetable oil production facility would be subject to the revised requirements for initial startup periods each year. However, we received comment on the proposed rule that some larger facilities may have significant modifications about once a year. Therefore, we have revised the costs associated with the final rule to assume that approximately eight existing vegetable oil production facilities (or approximately 10 percent of existing facilities) may have a significant modification that could require that they meet the revised requirements for initial startup periods. The revised assumption results in an increase in the total nationwide annual costs associated with the final requirements to account for the additional facilities anticipated to have a significant modification (actual costs per facility have not changed). For further information on the costs and cost savings associated with the final requirements, see the memorandum, *Cost for the Solvent Extraction for Vegetable Oil Production Source Category Risk and Technology Review—Final Amendments,* and the document, *Supporting Statement for NESHAP for Solvent Extraction for Vegetable Oil Production,* which are both available in the docket for this action.

D. What are the economic impacts?

Economic impact analyses focus on changes in market prices and output levels. If changes in market prices and output levels in the primary markets are significant enough, impacts on other markets may also be examined. Both the magnitude of costs needed to comply with a final rule and the distribution of these costs among affected facilities can have a role in determining how the market will change in response to a final rule. The total costs associated with the final rule are estimated to be $93,100 (or $31,033 per year) for the 3 years following the final rule. This includes a one-time burden for reviewing requirements of the amended rule, and a one-time burden associated with the recordkeeping and reporting for initial startup periods for new, reconstructed, or significantly modified facilities. This is an estimated average cost of approximately $345 per year per facility. These costs are not expected to result in a significant market impact, regardless of whether they are passed on to the purchaser or absorbed by the firms.

E. What are the benefits?

Although the EPA does not anticipate quantifiable reductions in HAP emissions as a result of the final amendments, we believe that the action will result in improvements to the rule. Specifically, the final amendments revise the standards such that they apply at all times. For facilities that choose to operate under an initial startup period, the EPA is finalizing an alternative work practice standard that will ensure that facilities are operating controls and minimizing emissions while the source operates under non-steady state production, which we expect will protect public health and the environment through better compliance during these periods. Additionally, the final amendments requiring electronic submittal of initial notifications, initial startup reports, annual compliance certifications, deviation reports, and performance test results will streamline reporting for affected sources, increase the usefulness of the data and improve data accessibility for the public, will further assist in the protection of public health and the environment, and will ultimately result in less burden on the regulated community. See section IV.D.2 of the preamble to the proposed rule for more information.

F. What analysis of environmental justice did we conduct?

As discussed in the preamble to the proposed rule, to examine the potential for any environmental justice issues that might be associated with the source category, we performed a demographic analysis, which is an assessment of risks to individual demographic groups of the populations living within 5 kilometers (km) and within 50 km of the facilities. In the analysis, we evaluated the distribution of HAP-related cancer and noncancer risks from the Solvent Extraction for Vegetable Oil Production source category across different demographic groups within the populations living near facilities. When examining the risk levels of those exposed to emissions from solvent extraction for vegetable oil production facilities, we found that no one is exposed to a cancer risk at or above 1-in-1 million or to a chronic noncancer TOSHI greater than 1.

The documentation for this decision is contained in section IV.A of the preamble to the proposed rule and the technical report titled *Risk and Technology Review—Analysis of Demographic Factors for Populations Living Near Solvent Extraction for Vegetable Oil Production,* which is available in the docket for this action.

G. What analysis of children's environmental health did we conduct?

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because the EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. This action's health and risk assessments are summarized in section IV.A of this preamble and are further documented in the risk report, *Residual Risk Assessment for the Solvent Extraction for Vegetable Oil Production Source Category in Support of the 2019 Risk and Technology Review Final Rule,* available in the docket for this action.

VI. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Orders 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action and was, therefore, not submitted to the Office of Management and Budget (OMB) for review.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is not an Executive Order 13771 regulatory action because this action is not significant under Executive Order 12866.

C. Paperwork Reduction Act (PRA)

The information collection activities in this rule have been submitted for approval to the OMB under the PRA. The Information Collection Request (ICR) document that the EPA prepared has been assigned EPA ICR number 1947.09. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here. The information collection requirements are not enforceable until OMB approves them.

The EPA is finalizing amendments that revise provisions pertaining to emissions during periods of SSM; add requirements for electronic reporting of certain notifications and reports and performance test results; and make other minor clarifications and corrections. This information will be collected to assure compliance with the Solvent

Extraction for Vegetable Oil Production NESHAP.

Respondents/affected entities: Owners or operators of vegetable oil production processes.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart GGGG).

Estimated number of respondents: 90 (assumes one new respondent over the next 3 years).

Frequency of response: Initially, occasionally, and annually.

Total estimated burden: The annual recordkeeping and reporting burden for responding facilities to comply with all of the requirements in the NESHAP, averaged over the 3 years of this ICR, is estimated to be 34,100 hours. Of these, 448 hours (per year) is the incremental burden to comply with the final rule amendments. Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: The annual recordkeeping and reporting cost for responding facilities to comply with all of the requirements in the NESHAP, averaged over the 3 years of this ICR, is estimated to be $3,490,000 (per year), including $0 annualized capital or operation and maintenance costs. Of the total, $31,033 (per year) is the incremental cost to comply with the final amendments to the rule, or approximately $345 per facility.

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 the EPA's regulations in 40 CFR are listed in 40 CFR part 9. When OMB approves this ICR, the Agency will announce that approval in the **Federal Register** and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities contained in this final rule.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. The small entities subject to the requirements of this action are small vegetable oil production facilities. The Agency has determined that up to 12 small entities, representing approximately 13 percent of the total number of entities subject to the final rule, may experience an impact of less than 1 percent of revenues. See section V.D of this preamble for additional information on the economic impacts of this action.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local, or tribal governments or the private sector.

F. Executive Order 13132: Federalism

This action does not have federalism implications. It will not 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.

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175. None of the solvent extraction for vegetable oil production facilities that have been identified as being affected by this final action are owned or operated by tribal governments or located within tribal lands. Thus, Executive Order 13175 does not apply to this action.

H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 because the EPA does not believe the environmental health risks or safety risks addressed by this action present a disproportionate risk to children. This action's health and risk assessments are contained in sections IV.A of this preamble and the document, *Residual Risk Assessment for the Solvent Extraction for Vegetable Oil Production Source Category in Support of the 2019 Risk and Technology Review Final Rule,* which is available in the docket for this rulemaking.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

J. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking involves technical standards. As discussed in the preamble of the proposal, the EPA conducted searches for the Solvent Extraction for Vegetable Oil Production Sector Risk and Technology Review through the Enhanced National Standards Systems Network Database managed by the American National Standards Institute (ANSI). We also contacted voluntary consensus standards (VCS) organizations and accessed and searched their databases. We conducted searches for EPA Method 311 of 40 CFR part 63, appendix A. No applicable VCS were identified for EPA Method 311. The search identified two VCS that were potentially applicable for this rule in lieu of EPA reference methods. After reviewing the available standards, the EPA determined that the two candidate VCS (ASTM D6438 (1999), CARB Method 310)) identified for measuring emissions of pollutants or their surrogates subject to emissions standards in the rule would not be practical due to lack of equivalency, documentation, validation data, and other important technical and policy considerations.

A thorough summary of the search conducted, and results are included in the memorandum, *Voluntary Consensus Standard Results for National Emission Standards for Hazardous Air Pollutants for Solvent Extraction for Vegetable Oil Production,* which is available in the docket for this action.

K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations, and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994).

The documentation for this decision is contained in section IV.A of this preamble and in the technical report, *Risk and Technology Review—Analysis of Demographic Factors for Populations Living Near Vegetable Oil Production Facilities,* available in the docket for this action.

L. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 63

Environmental protection, Air pollution control, Hazardous substances, Reporting and recordkeeping requirements.

Dated: February 25, 2020.

Andrew R. Wheeler,

Administrator.

For the reasons set forth in the preamble, the EPA is amending 40 CFR part 63 as follows:

PART 63—NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR SOURCE CATEGORIES

■ 1. The authority citation for part 63 continues to read as follows:

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

Subpart GGGG—National Emission Standards for Hazardous Air Pollutants: Solvent Extraction for Vegetable Oil Production

■ 2. Section 63.2834 is amended by revising Table 1 of § 63.2834 to read as follows:

§ 63.2834 When do I have to comply with the standards in this subpart?

* * * * *

TABLE 1 OF § 63.2834—COMPLIANCE DATES FOR EXISTING AND NEW SOURCES

If your affected source is categorized as . . .	And if . . .	Then your compliance date is . . .	Except for certain requirements, as specified in §§ 63.2840, 63.2850, 63.2851, 63.2852, 63.2853, 63.2861, 63.2862, and 63.2870, then your compliance date is . . .
(a) an existing source		April 12, 2004	September 15, 2020.
(b) a new source	you startup your affected source before April 12, 2001.	April 12, 2004	September 15, 2020.
(c) a new source	you startup your affected source on or after April 12, 2001, but before March 18, 2020.	your startup date	September 15, 2020.
(d) a new source	you startup your affected source on or after March 18, 2020.	your startup date	your startup date.

■ 3. Section 63.2840 is amended by:

■ a. Revising the introductory text and paragraphs (a)(1) introductory text and (b) introductory text;

■ b. Removing and reserving paragraph (b)(1);

■ c Revising paragraphs (b)(3) through (5); and

■ d. Adding paragraphs (g) and (h).

The revisions and additions read as follows:

§ 63.2840 What emission requirements must I meet?

For each facility meeting the applicability criteria in § 63.2832, you must comply with either the requirements specified in paragraphs (a) through (d), or the requirements in paragraph (e) of this section. You must also comply with the requirements in paragraph (g) of this section. You must comply with the work practice standard provided in paragraph (h) of this section, if you choose to operate your source under an initial startup period subject to § 63.2850(c)(2) or (d)(2).

(a)(1) The emission requirements limit the number of gallons of HAP lost per ton of listed oilseeds processed. For each operating month, as defined in § 63.2872, you must calculate a compliance ratio which compares your actual HAP loss to your allowable HAP loss for the previous 12 operating months as shown in Equation 1 of this section. Equation 1 of this section follows:

* * * * *

(b) When your source has processed listed oilseed for 12 operating months, calculate the compliance ratio by the end of each calendar month following an operating month, as defined in § 63.2872, using Equation 2 of this section. When calculating your compliance ratio, consider the conditions and exclusions in paragraphs (b)(1) through (6) of this section:

* * * * *

(3) If your source shuts down and processes no listed oilseed for an entire calendar or accounting month, then you must categorize the month as a nonoperating month, as defined in § 63.2872. Exclude any nonoperating months from the compliance ratio determination.

(4) If your source is subject to an initial startup period as defined in § 63.2872, you may exclude from the compliance ratio determination any solvent and oilseed information recorded for the initial startup period, provided you meet the work practice standard in § 63.2850(c)(2) or (d)(2).

(5) Before September 15, 2020, if your source is subject to a malfunction period as defined in § 63.2872, exclude from the compliance ratio determination any solvent and oilseed information recorded for the malfunction period. The provisions of this paragraph (e) do not apply on and after September 15, 2020.

* * * * *

(g) On or after September 15, 2020, you must operate and maintain any affected source, including associated air pollution control equipment and monitoring equipment, at all times in a manner consistent with safety and good air pollution control practices for minimizing emissions. The general duty to minimize emissions does not require you to make any further efforts to reduce emissions if levels required by the applicable standard have been achieved. Determination of whether a source is operating in compliance with operation and maintenance requirements will be based on information available to the Administrator which may include, but is not limited to, monitoring results, review of operation and maintenance procedures, review of operation and maintenance records, and inspection of the source.

(h) On and after September 15, 2020, you must meet the requirements in paragraphs (h)(1) through (3) of this section if you choose to operate your source under an initial startup period subject to § 63.2850(c)(2) or (d)(2).

(1) You must operate the mineral oil absorption system at all times during the initial startup period unless doing so is not possible due to safety considerations;

(2) You must operate the solvent condensers at all times during the initial startup period unless doing so is not possible due to safety considerations; and

(3) You must follow site-specific operating limits, established according to the requirements in paragraphs

(h)(3)(i) and (ii) of this section, for temperature and pressure for the desolventizing and oil distillation units associated with solvent recovery at all times, unless doing so is not possible due to safety considerations.

(i) Your site-specific operating limits may be based on equipment design, manufacturer's recommendations, or other site-specific operating values established for normal operating periods.

(ii) The operating limits may be in the form of a minimum, maximum, or operating range.

■ 4. Section 63.2850 is amended by:

■ a. Revising paragraph (a)(3) and paragraph (a)(5) introductory text;

■ b. Adding paragraph (a)(5)(iv);

■ c. Revising paragraphs (b), (c)(1) and (2), (d)(1) and (2), (e) introductory text, and (e)(2); and

■ d. Revising Table 1 of § 63.2850.

The revisions and addition read as follows:

§ 63.2850 How do I comply with the hazardous air pollutant emission standards?

(a) * * *

(3) Develop a written startup, shutdown and malfunction (SSM) plan in accordance with the provisions in § 63.2852. On and after September 15, 2020, an SSM plan is not required.

* * * * *

(5) Submit the reports in paragraphs (a)(5)(i) through (iv) of this section, as applicable:

* * * * *

(iv) Initial startup period reports in accordance with § 63.2861(e).

* * * * *

(b) *Existing sources under normal operation.* You must meet all of the requirements listed in paragraph (a) of this section and Table 1 of this section for sources under normal operation, and the schedules for demonstrating compliance for existing sources under normal operation in Table 2 of this section.

(c) * * *

(1) *Normal operation.* Upon initial startup of your new source, you must meet all of the requirements listed in § 63.2850(a) and Table 1 of this section for sources under normal operation, and the schedules for demonstrating compliance for new sources under normal operation in Table 2 of this section.

(2) *Initial startup period.* For up to 6 calendar months after the startup date of your new source, you must meet all of the requirements listed in paragraph (a) of this section and Table 1 of this section for sources operating under an initial startup period, and the schedules for demonstrating compliance for new sources operating under an initial startup period in Table 2 of this section. On and after September 15, 2020, you must also comply with the work practice standard in § 63.2840(h) for the duration of the initial startup period. At the end of the initial startup period (as defined in § 63.2872), your new source must then meet all of the requirements listed in Table 1 of this section for sources under normal operation.

(d) * * *

(1) *Normal operation.* Upon initial startup of your significantly modified existing or new source, you must meet all of the requirements listed in paragraph (a) of this section and Table 1 of this section for sources under normal operation, and the schedules for demonstrating compliance for an existing or new source that has been significantly modified in Table 2 of this section.

(2) *Initial startup period.* For up to 3 calendar months after the startup date of your significantly modified existing or new source, you must meet all of the requirements listed in paragraph (a) of this section and Table 1 of this section for sources operating under an initial startup period, and the schedules for demonstrating compliance for a significantly modified existing or new source operating under an initial startup period in Table 2 of this section. On and after September 15, 2020, you must also comply with the work practice standard in § 63.2840(h) for the duration of the initial startup period. At the end of the initial startup period (as defined in § 63.2872), your new or existing source must meet all of the requirements listed in Table 1 of this section for sources under normal operation.

(e) *Existing or new sources experiencing a malfunction.* A *malfunction* is defined in § 63.2. In general, it means any sudden, infrequent, and not reasonably preventable failure of air pollution control equipment, process equipment, or a process to function in a normal or usual manner. If your existing or new source experiences an unscheduled shutdown as a result of a malfunction, continues to operate during a malfunction (including the period reasonably necessary to correct the malfunction), or starts up after a shutdown resulting from a malfunction, then you must meet the requirements associated with one of two compliance options. Routine or scheduled process startups and shutdowns resulting from, but not limited to, market demands, maintenance activities, and switching types of oilseed processed, are not startups or shutdowns resulting from a malfunction and, therefore, do not qualify for this provision. Within 15 days of the beginning date of the malfunction, you must choose to comply with one of the options listed in paragraphs (e)(1) and (2) of this section. The provisions of this paragraph (e) do not apply on and after September 15, 2020.

* * * * *

(2) *Malfunction period.* Throughout the malfunction period, you must meet all of the requirements listed in paragraph (a) of this section and Table 1 of this section for sources operating during a malfunction period. At the end of the malfunction period, your source must then meet all of the requirements listed in Table 1 of this section for sources under normal operation. Table 1 of this section follows:

TABLE 1 OF § 63.2850—REQUIREMENTS FOR COMPLIANCE WITH HAP EMISSION STANDARDS

Are you required to . . .	For periods of normal operation? [a]	For initial startup periods subject to § 63.2850(c)(2) or (d)(2)?	Before September 15, 2020, for malfunction periods subject to § 63.2850(e)(2)? [a]
(a)(1) Operate and maintain your source in accordance with general duty provisions of § 63.6(e) before September 15, 2020?	Yes. Additionally, the HAP emission limits will apply.	Yes, you are required to minimize emissions to the extent practicable throughout the initial startup period. Such measures should be described in the SSM plan.	Yes, you are required to minimize emissions to the extent practicable throughout the initial startup period. Such measures should be described in the SSM plan.

TABLE 1 OF § 63.2850—REQUIREMENTS FOR COMPLIANCE WITH HAP EMISSION STANDARDS—Continued

Are you required to . . .	For periods of normal operation? [a]	For initial startup periods subject to § 63.2850(c)(2) or (d)(2)?	Before September 15, 2020, for malfunction periods subject to § 63.2850(e)(2)? [a]
(a)(2) Operate and maintain your source in accordance with general duty provisions of § 63.6(e) on and after September 15, 2020?	No, you must meet the requirements of § 63.2840(g). Additionally, the HAP emission limits will apply.	No, you must meet the requirements of § 63.2840(g).	
(b) Determine and record the extraction solvent loss in gallons from your source?	Yes, as described in § 63.2853 ..	Yes, as described in § 63.2862(e) (before September 15, 2020) and § 63.2862(f) (on and after September 15, 2020).	Yes, as described in § 63.2862(e).
(c) Record the volume fraction of HAP present at greater than 1 percent by volume and gallons of extraction solvent in shipment received?	Yes	Yes	Yes.
(d) Determine and record the tons of each oilseed type processed by your source?	Yes, as described in § 63.2855 ..	No	No.
(e) Determine the weighted average volume fraction of HAP in extraction solvent received as described in § 63.2854 by the end of the following calendar month?	Yes	No. Except for solvent received by a new or reconstructed source commencing operation under an initial startup period, the HAP volume fraction in any solvent received during an initial startup period is included in the weighted average HAP determination for the next operating month.	No, the HAP volume fraction in any solvent received during a malfunction period is included in the weighted average HAP determination for the next operating month.
(f) Determine and record the actual solvent loss, weighted average volume fraction HAP, oilseed processed and compliance ratio for each 12 operating month period as described in § 63.2840 by the end of the following calendar month?	Yes	No, these requirements are not applicable because your source is not required to determine the compliance ratio with data recorded for an initial startup period.	No, these requirements are not applicable because your source is not required to determine the compliance ratio with data recorded for a malfunction period.
(g) Submit a Notification of Compliance Status or Annual Compliance Certification as appropriate?	Yes, as described in §§ 63.2860(d) and 63.2861(a).	No. However, you may be required to submit an annual compliance certification for previous operating months, if the deadline for the annual compliance certification happens to occur during the initial startup period.	No. However, you may be required to submit an annual compliance certification for previous operating months, if the deadline for the annual compliance certification happens to occur during the malfunction period.
(h)(1) Submit a Deviation Notification Report by the end of the calendar month following the month in which you determined that the compliance ratio exceeds 1.00 as described in § 63.2861(b) before September 15, 2020?	Yes	No, these requirements are not applicable because your source is not required to determine the compliance ratio with data recorded for an initial startup period.	No, these requirements are not applicable because your source is not required to determine the compliance ratio with data recorded for a malfunction period.
(h)(2) Submit a Deviation Notification Report as described in § 63.2861(b) on and after September 15, 2020?	Yes	Yes	No.
(i) Submit a Periodic SSM Report as described in § 63.2861(c)?	No, a SSM activity is not categorized as normal operation.	Yes, before September 15, 2020	Yes.
(j) Submit an Immediate SSM Report as described in § 63.2861(d)?	No, a SSM activity is not categorized as normal operation.	Yes, only before September 15, 2020 and if your source does not follow the SSM plan.	Yes, only if your source does not follow the SSM plan.
(k) Submit an Initial Startup Report as described in § 63.2861(e) on and after September 15, 2020?	No	Yes	No.

[a] Beginning on September 15, 2020, you must meet the requirements of this table for normal operating periods or for initial startup periods subject to § 63.2850(c)(2) or (d)(2) at all times. The column ''For malfunction periods subject to § 63.2850(e)(2)?'' is not applicable beginning on September 15, 2020.

■ 5. Section 63.2851 is amended by revising paragraph (a) introductory text and adding paragraph (a)(8) to read as follows:

§ 63.2851 What is a plan for demonstrating compliance?

(a) You must develop and implement a written plan for demonstrating compliance that provides the detailed procedures you will follow to monitor and record data necessary for demonstrating compliance with this subpart. Procedures followed for quantifying solvent loss from the source and amount of oilseed processed vary from source to source because of site-specific factors such as equipment design characteristics and operating conditions. Typical procedures include one or more accurate measurement methods such as weigh scales, volumetric displacement, and material mass balances. Because the industry does not have a uniform set of procedures, you must develop and implement your own site-specific plan for demonstrating compliance before the compliance date for your source. You must also incorporate the plan for demonstrating compliance by reference in the source's title V permit and keep the plan on-site and readily available as long as the source is operational. If you make any changes to the plan for demonstrating compliance, then you must keep all previous versions of the plan and make them readily available for inspection for at least 5 years after each revision. The plan for demonstrating compliance must include the items in paragraphs (a)(1) through (8) of this section:

* * * * *

(8) On and after September 15, 2020, if you choose to operate your source under an initial start-up period subject to § 63.2850(c)(2) or (d)(2), the items in paragraphs (c)(8)(i) and (ii) of this section:

(i) Your site-specific operating limits, and their basis, for temperature and pressure for the desolventizing and oil distillation units associated with solvent recovery.

(ii) A detailed description of all methods of measurement your source will use to measure temperature and pressure, including the measurement frequency.

* * * * *

■ 6. Section 63.2852 is revised to read as follows:

§ 63.2852 What is a startup, shutdown, and malfunction plan?

Before September 15, 2020, you must develop a written SSM plan in accordance with § 63.6(e)(3). You must complete the SSM plan before the compliance date for your source. You must also keep the SSM plan on-site and readily available as long as the source is operational. The SSM plan provides detailed procedures for operating and maintaining your source to minimize emissions during a qualifying SSM event for which the source chooses the § 63.2850(e)(2) malfunction period, or the § 63.2850(c)(2) or (d)(2) initial startup period. The SSM plan must specify a program of corrective action for malfunctioning process and air pollution control equipment and reflect the best practices now in use by the industry to minimize emissions. Some or all of the procedures may come from plans you developed for other purposes such as a Standard Operating Procedure manual or an Occupational Safety and Health Administration Process Safety Management plan. To qualify as a SSM plan, other such plans must meet all the applicable requirements of these NESHAP. The provisions of this section do not apply on and after September 15, 2020.

■ 7. Section 63.2853 is amended by:

■ a. Revising paragraph (a)(2) introductory text;

■ b. Revising the heading for Table 1 of § 63.2853 in paragraph (a)(2);

■ c. Adding Table 2 of § 63.2853(a)(2) to paragraph (a)(2); and

■ d. Revising paragraphs (a)(3), (a)(5)(i), and (c)(1), (3), and (4).

The revisions and addition read as follows:

§ 63.2853 How do I determine the actual solvent loss?

* * * * *

(a) * * *

(2) *Source operating status.* You must categorize the operating status of your source for each recorded time interval in accordance with criteria in Table 1 or Table 2 of this section, as follows:

TABLE 1 OF § 63.2853(a)(2)—CATEGORIZING YOUR SOURCE OPERATING STATUS BEFORE SEPTEMBER 15, 2020

* * * * *

TABLE 2 OF § 63.2853(a)(2)—CATEGORIZING YOUR SOURCE OPERATING STATUS ON AND AFTER SEPTEMBER 15, 2020

If during a recorded time interval . . .	Then your source operating status is . . .
(vi) Your source processes any amount of listed oilseed and source is not operating under an initial startup operating period subject to § 63.2850(c)(2) or (d)(2).	A normal operating period.
(vii) Your source processes no agricultural product and your source is not operating under an initial startup period subject to § 63.2850(c)(2) or (d)(2).	A nonoperating period.
(viii) You choose to operate your source under an initial startup period subject to § 63.2850(c)(2) or (d)(2) ..	An initial startup period.
(ix) Your source processes agricultural products not defined as listed oilseed	An exempt period.

(3) *Measuring the beginning and ending solvent inventory.* You are required to measure and record the solvent inventory on the beginning and ending dates of each normal operating period that occurs during an operating month. You must consistently follow the procedures described in your plan for demonstrating compliance, as specified in § 63.2851, to determine the extraction solvent inventory, and maintain readily available records of the actual solvent loss inventory, as described in § 63.2862(c)(1). In general, you must measure and record the solvent inventory only when the source is actively processing any type of agricultural product. When the source is not active, some or all of the solvent working capacity is transferred to solvent storage tanks which can artificially inflate the solvent inventory.

* * * * *

(5) * * *

(i) *Solvent destroyed in a control device.* You may use a control device to reduce solvent emissions to meet the emission standard. The use of a control device does not alter the emission limit for the source. If you use a control device that reduces solvent emissions through destruction of the solvent instead of recovery, then determine the gallons of solvent that enter the control device and are destroyed there during each normal operating period. All

solvent destroyed in a control device during a normal operating period can be subtracted from the total solvent loss. Examples of destructive emission control devices include catalytic incinerators, boilers, or flares. Identify and describe, in your plan for demonstrating compliance, each type of reasonable and sound measurement method that you use to quantify the gallons of solvent entering and exiting the control device and to determine the destruction efficiency of the control device. You may use design evaluations to document the gallons of solvent destroyed or removed by the control device instead of performance testing under § 63.7. The design evaluations must be based on the procedures and options described in § 63.985(b)(1)(i)(A) through (C) or § 63.11, as appropriate. All data, assumptions, and procedures used in such evaluations must be documented and available for inspection. If you use performance testing to determine solvent flow rate to the control device or destruction efficiency of the device, follow the procedures as outlined in § 63.997(e)(1) and (2) and the requirements in paragraph (a)(5)(i)(A) of this section. Instead of periodic performance testing to demonstrate continued good operation of the control device, you may develop a monitoring plan, following the procedures outlined in § 63.988(c) and using operational parametric measurement devices such as fan parameters, percent measurements of lower explosive limits, and combustion temperature.

(A) On or after September 15, 2020, you must conduct all performance tests under such conditions as the Administrator specifies to you based on representative performance of the affected source for the period being tested. Representative conditions exclude periods of startup and shutdown unless specified by the Administrator. You may not conduct performance tests during periods of malfunction. You must record the process information that is necessary to document operating conditions during the test and include in such record an explanation to support that such conditions represent normal operation. Upon request, you shall make available to the Administrator such records as may be necessary to determine the conditions of performance tests.

(B) [Reserved]

(c) * * *

(1) Nonoperating periods as described in paragraph (a)(2) of this section.

* * * * *

(3) Before September 15, 2020, malfunction periods as described in § 63.2850(e)(2).

(4) Exempt operation periods as described in paragraph (a)(2) of this section.

■ 8. Section 63.2855 is amended by revising paragraphs (a)(3), (a)(5)(i), and (c)(3) to read as follows:

§ 63.2855 How do I determine the quantity of oilseed processed?

* * * * *

(a) * * *

(3) *Measuring the beginning and ending inventory for each oilseed.* You are required to measure and record the oilseed inventory on the beginning and ending dates of each normal operating period that occurs during an operating month. You must consistently follow the procedures described in your plan for demonstrating compliance, as specified in § 63.2851, to determine the oilseed inventory on an as received basis and maintain readily available records of the oilseed inventory as described by § 63.2862(c)(3).

* * * * *

(5) * * *

(i) Oilseed that molds or otherwise become unsuitable for processing.

* * * * *

(c) * * *

(3) Before September 15, 2020, malfunction periods as described in § 63.2850(e)(2).

* * * * *

■ 9. Section 63.2861 is amended by

■ a. Revising paragraph (b) introductory text;

■ b. Adding paragraphs (b)(5) through (8);

■ c. Revising paragraphs (c) introductory text and (d) introductory text; and

■ d. Adding paragraphs (e) through (i).

The revisions and additions read as follows:

§ 63.2861 What reports must I submit and when?

* * * * *

(b) *Deviation notification report.* Submit a deviation report for each compliance determination you make in which the compliance ratio exceeds 1.00 as determined under § 63.2840(c) or if you deviate from the work practice standard for an initial startup period subject to § 63.2850(c)(2) or (d)(2). Submit the deviation report by the end of the month following the calendar month in which you determined the deviation. The deviation notification report must include the items in paragraphs (b)(1) through (7) of this section if you exceed the compliance ratio, and must include the items in paragraphs (b)(1), (2), and (5) through (8) of this section if you deviate from the work practice standard:

* * * * *

(5) Beginning on September 15, 2020, the number of deviations and for each deviation the date and duration of each deviation. Flag and provide an explanation for any deviation from the compliance ratio for which a deviation report is being submitted for more than one consecutive month (*i.e.,* include a reference to the original date and reporting of the deviation). If the explanation provides that corrective actions have returned the affected unit(s) to its normal operation, you are not required to include the items in paragraphs (b)(6) and (7) of this section.

(6) Beginning on September 15, 2020, a statement of the cause of each deviation (including unknown cause, if applicable).

(7) Beginning on September 15, 2020, for each deviation, a list of the affected sources or equipment, an estimate of the quantity of HAP emitted over the emission requirements of § 63.2840, and a description of the method used to estimate the emissions.

(8) A description of the deviation from the work practice standard during the initial startup period, including the records of § 63.2862(f) for the deviation.

(c) *Periodic startup, shutdown, and malfunction report.* Before September 15, 2020, if you choose to operate your source under an initial startup period subject to § 63.2850(c)(2) or (d)(2) or a malfunction period subject to § 63.2850(e)(2), you must submit a periodic SSM report by the end of the calendar month following each month in which the initial startup period or malfunction period occurred. The periodic SSM report must include the items in paragraphs (c)(1) through (3) of this section. The provisions of this paragraph (c) do not apply on and after September 15, 2020.

* * * * *

(d) *Immediate SSM reports.* Before September 15, 2020, if you handle a SSM during an initial startup period subject to § 63.2850(c)(2) or (d)(2) or a malfunction period subject to § 63.2850(e)(2) differently from procedures in the SSM plan and the relevant emission requirements in § 63.2840 are exceeded, then you must submit an immediate SSM report. Immediate SSM reports consist of a telephone call or facsimile transmission to the responsible agency within 2 working days after starting actions inconsistent with the SSM plan, followed by a letter within 7 working

days after the end of the event. The letter must include the items in paragraphs (d)(1) through (3) of this section. The provisions of this paragraph (d) do not apply on and after September 15, 2020.

* * * * *

(e) *Initial startup period reports.* If you choose to operate your source under an initial startup period subject to § 63.2850(c)(2) or (d)(2) on and after September 15, 2020, you must submit an initial startup period report within 30 days after the initial startup period ends. The report must include the items in paragraphs (e)(1) through (3) of this section.

(1) The name and address of the owner or operator.

(2) The physical address of the vegetable oil production process.

(3) A compliance certification indicating whether the source was in compliance with the work practice standard of § 63.2840(h).

(f) *Performance tests.* On and after September 15, 2020, if you conduct performance tests to determine solvent flow rate to a control device or destruction efficiency of a control device according to the requirements of § 63.2853(a)(5)(i), within 60 days after the date of completing each performance test, you must submit the results of the performance test following the procedures specified in paragraphs (f)(1) and (2) of this section.

(1) *Data collected using test methods supported by EPA's Electronic Reporting Tool (ERT) as listed on EPA's ERT website (https://www.epa.gov/electronic-reporting-air-emissions/electronic-reporting-tool-ert) at the time of the test.* Submit the results of the performance test to EPA via the Compliance and Emissions Data Reporting Interface (CEDRI), which can be accessed through EPA's Central Data Exchange (CDX) (*https://cdx.epa.gov/*). The data must be submitted in a file format generated through the use of EPA's ERT. Alternatively, you may submit an electronic file consistent with the extensible markup language (XML) schema listed on EPA's ERT website.

(2) *Data collected using test methods that are not supported by EPA's ERT as listed on EPA's ERT website at the time of the test.* The results of the performance test must be included as an attachment in the ERT or an alternate electronic file consistent with the XML schema listed on EPA's ERT website. Submit the ERT generated package or alternative file to EPA via CEDRI.

(3) *Confidential business information (CBI).* If you claim some of the information submitted under paragraph (f) or (g) of this section is CBI, you must submit a complete file, including information claimed to be CBI, to EPA. The file must be generated through the use of EPA's ERT or an alternate electronic file consistent with the XML schema listed on EPA's ERT website. Submit the file on a compact disc, flash drive, or other commonly used electronic storage medium and clearly mark the medium as CBI. Mail the electronic medium to U.S. EPA/OAQPS/CORE CBI Office, Attention: Group Leader, Measurement Policy Group, MD C404–02, 4930 Old Page Rd., Durham, NC 27703. The same file with the CBI omitted must be submitted to EPA via EPA's CDX as described in paragraph (f)(1) of this section.

(g) *Submitting reports electronically.* On and after September 15, 2020, you must submit the initial notification required in § 63.2860(b) and the annual compliance certification, deviation report, and initial startup report required in § 63.2861(a), (b), and (e) to the EPA via CEDRI, which can be accessed through the EPA's CDX (*https://cdx.epa.gov*). The owner or operator must upload to CEDRI an electronic copy of each applicable notification in portable document format (PDF). The applicable notification must be submitted by the deadline specified in this subpart, regardless of the method in which the reports are submitted. You must use the appropriate electronic report template on the CEDRI website (*https://www.epa.gov/electronic-reporting-air-emissions/compliance-and-emissions-data-reporting-interface-cedri*) for this subpart. The date report templates become available will be listed on the CEDRI website. The report must be submitted by the deadline specified in this subpart, regardless of the method in which the report is submitted. If you claim some of the information required to be submitted via CEDRI is CBI, submit a complete report, including information claimed to be CBI, to EPA. The report must be generated using the appropriate form on the CEDRI website. Submit the file on a compact disc, flash drive, or other commonly used electronic storage medium and clearly mark the medium as CBI. Mail the electronic medium to U.S. EPA/OAQPS/CORE CBI Office, Attention: Group Leader, Measurement Policy Group, MD C404–02, 4930 Old Page Rd., Durham, NC 27703. The same file with the CBI omitted must be submitted to EPA via EPA's CDX as described earlier in this paragraph.

(h) *Claims of EPA system outage.* If you are required to electronically submit a report through CEDRI in EPA's CDX, you may assert a claim of EPA system outage for failure to timely comply with the reporting requirement. To assert a claim of EPA system outage, you must meet the requirements outlined in paragraphs (h)(1) through (7) of this section.

(1) You must have been or will be precluded from accessing CEDRI and submitting a required report within the time prescribed due to an outage of either EPA's CEDRI or CDX systems.

(2) The outage must have occurred within the period of time beginning five business days prior to the date that the submission is due.

(3) The outage may be planned or unplanned.

(4) You must submit notification to the Administrator in writing as soon as possible following the date you first knew, or through due diligence should have known, that the event may cause or has caused a delay in reporting.

(5) You must provide to the Administrator a written description identifying:

(i) The date(s) and time(s) when CDX or CEDRI was accessed and the system was unavailable;

(ii) A rationale for attributing the delay in reporting beyond the regulatory deadline to EPA system outage;

(iii) Measures taken or to be taken to minimize the delay in reporting; and

(iv) The date by which you propose to report, or if you have already met the reporting requirement at the time of the notification, the date you reported.

(6) The decision to accept the claim of EPA system outage and allow an extension to the reporting deadline is solely within the discretion of the Administrator.

(7) In any circumstance, the report must be submitted electronically as soon as possible after the outage is resolved.

(i) *Claims of force majeure.* If you are required to electronically submit a report through CEDRI in EPA's CDX, you may assert a claim of force majeure for failure to timely comply with the reporting requirement. To assert a claim of force majeure, you must meet the requirements outlined in paragraphs (i)(1) through (5) of this section.

(1) You may submit a claim if a force majeure event is about to occur, occurs, or has occurred or there are lingering effects from such an event within the period of time beginning five business days prior to the date the submission is due. For the purposes of this section, a force majeure event is defined as an event that will be or has been caused by circumstances beyond the control of the affected facility, its contractors, or any entity controlled by the affected facility

that prevents you from complying with the requirement to submit a report electronically within the time period prescribed. Examples of such events are acts of nature (*e.g.,* hurricanes, earthquakes, or floods), acts of war or terrorism, or equipment failure or safety hazard beyond the control of the affected facility (*e.g.,* large scale power outage).

(2) You must submit notification to the Administrator in writing as soon as possible following the date you first knew, or through due diligence should have known, that the event may cause or has caused a delay in reporting.

(3) You must provide to the Administrator:

(i) A written description of the force majeure event;

(ii) A rationale for attributing the delay in reporting beyond the regulatory deadline to the force majeure event;

(iii) Measures taken or to be taken to minimize the delay in reporting; and

(iv) The date by which you propose to report, or if you have already met the reporting requirement at the time of the notification, the date you reported.

(4) The decision to accept the claim of force majeure and allow an extension to the reporting deadline is solely within the discretion of the Administrator.

(5) In any circumstance, the reporting must occur as soon as possible after the force majeure event occurs.

■ 10. Section 63.2862 is amended by:

■ a. Revising paragraph (b) and paragraph (c) introductory text;

■ b. Revising paragraphs (c)(3)(ii), (d) introductory text, and (e) introductory text; and

■ c. Adding paragraphs (f) through (h).

The revisions and additions read as follows:

§ 63.2862 What records must I keep?

* * * * *

(b) Before September 15, 2020, prepare a plan for demonstrating compliance (as described in § 63.2851) and a SSM plan (as described in § 63.2852). In these two plans, describe the procedures you will follow in obtaining and recording data, and determining compliance under normal operations or a SSM subject to the § 63.2850(c)(2) or (d)(2) initial startup period or the § 63.2850(e)(2) malfunction period. Complete both plans before the compliance date for your source and keep them on-site and readily available as long as the source is operational. On and after September 15, 2020, the requirement to prepare a SSM plan no longer applies, and the plan for demonstrating compliance must only describe the procedures you develop according to the requirements of § 63.2851.

(c) If your source processes any listed oilseed, record the items in paragraphs (c)(1) through (3) of this section:

* * * * *

(3) * * *

(ii) The operating status of your source, as described in § 63.2853(a)(2). On the log for each type of listed oilseed that is not being processed during a normal operating period, you must record which type of listed oilseed is being processed in addition to the source operating status.

* * * * *

(d) After your source has processed listed oilseed for 12 operating months, record the items in paragraphs (d)(1) through (5) of this section by the end of the calendar month following each operating month:

* * * * *

(e) Before September 15, 2020, for each SSM event subject to an initial startup period as described in § 63.2850(c)(2) or (d)(2), or a malfunction period as described in § 63.2850(e)(2), record the items in paragraphs (e)(1) through (3) of this section by the end of the calendar month following each month in which the initial startup period or malfunction period occurred. The provisions of this paragraph (e) do not apply on and after September 15, 2020.

* * * * *

(f) On and after September 15, 2020, for each initial startup period subject to § 63.2850(c)(2) or (d)(2), record the items in paragraphs (f)(1) through (6) of this section by the end of the calendar month following each month in which the initial startup period occurred.

(1) A description and dates of the initial startup period, and reason it qualifies as an initial startup.

(2) An estimate of the solvent loss in gallons for the duration of the initial startup or malfunction period with supporting documentation.

(3) Nominal design rate of the extractor and operating rate of the extractor for the duration of the initial startup period, or permitted production rate and actual production rate of your source for the duration of the initial startup period.

(4) Measured values for temperature and pressure for the desolventizing and oil distillation units associated with solvent recovery.

(5) Information to indicate the mineral oil absorption system was operating at all times during the initial startup period.

(6) Information to indicate the solvent condensers were operating at all times during the initial startup period.

(g) On and after September 15, 2020, keep the records of deviations specified in paragraphs (f)(1) through (4) of this section for each compliance determination you make in which the compliance ratio exceeds 1.00 as determined under § 63.2840(c) or if you deviate from the work practice standard for an initial startup period subject to § 63.2850(c)(2) or (d)(2).

(1) The number of deviations, and the date and duration of each deviation. For deviations from the compliance ratio, the date of the deviation is the date the compliance ratio determination is made. The duration of the deviation from the compliance ratio is the length of time taken to address the cause of the deviation, including the duration of any malfunction, and return the affected unit(s) to its normal or usual manner of operation. For deviations from the work practice standard during the initial startup period, the date of the deviation is the date(s) when the facility fails to comply with any of the work practice standard in § 63.2840(h). The duration of the deviation from the work practice standard is the length of time taken to return to the work practice standards.

(2) A statement of the cause of each deviation (including unknown cause, if applicable).

(3) For each deviation, a list of the affected sources or equipment, an estimate of the quantity of each regulated pollutant emitted over any emission limit, and a description of the method used to estimate the emissions.

(4) Actions taken to minimize emissions in accordance with § 63.2840(g), and any corrective actions taken to return the affected unit to its normal or usual manner of operation.

(5) If you deviate from the work practice standard for an initial startup period, a description of the deviation from the work practice standard.

(h) Any records required to be maintained by this part that are submitted electronically via EPA's CEDRI may be maintained in electronic format. This ability to maintain electronic copies does not affect the requirement for facilities to make records, data, and reports available upon request to a delegated air agency or EPA as part of an on-site compliance evaluation.

■ 11. Section 63.2870 is amended by revising Table 1 to § 63.2870 to read as follows:

§ 63.2870 What parts of the General Provisions apply to me?

* * * * *

TABLE 1 TO § 63.2870—APPLICABILITY OF 40 CFR PART 63, SUBPART A, TO 40 CFR, PART 63, SUBPART GGGG

General provisions citation	Subject of citation	Brief description of requirement	Applies to subpart	Explanation
§ 63.1	Applicability	Initial applicability determination; applicability after standard established; permit requirements; extensions; notifications.	Yes.	
§ 63.2	Definitions	Definitions for part 63 standards.	Yes	Except as specifically provided in this subpart.
§ 63.3	Units and abbreviations.	Units and abbreviations for part 63 standards.	Yes.	
§ 63.4	Prohibited activities and circumvention.	Prohibited activities; compliance date; circumvention; severability.	Yes.	
§ 63.5	Construction/reconstruction.	Applicability; applications; approvals.	Yes	Except for subsections of § 63.5 as listed below.
§ 63.5(c)	[Reserved].			
§ 63.5(d)(1)(ii)(H)	Application for approval.	Type and quantity of HAP, operating parameters.	No	All sources emit HAP. Subpart GGGG does not require control from specific emission points.
§ 63.5(d)(1)(ii)(I)	[Reserved].			
§ 63.5(d)(1)(iii), (d)(2), (d)(3)(ii).		Application for approval.	No	The requirements of the application for approval for new, reconstructed and significantly modified sources are described in § 63.2860(b) and (c) of subpart GGGG. General provision requirements for identification of HAP emission points or estimates of actual emissions are not required. Descriptions of control and methods, and the estimated and actual control efficiency of such do not apply. Requirements for describing control equipment and the estimated and actual control efficiency of such equipment apply only to control equipment to which the subpart GGGG requirements for quantifying.
§ 63.6	Applicability of General Provisions.	Applicability	Yes	Except for subsections of § 63.6 as listed below.
§ 63.6(b)(1)–(3)	Compliance dates, new and reconstructed sources.		No	Section 63.2834 of subpart GGGG specifies the compliance dates for new and reconstructed sources.
§ 63.6(b)(6)	[Reserved].			
§ 63.6(c)(3)–(4)	[Reserved].			
§ 63.6(d)	[Reserved].			
§ 63.6(e)(1)(i)	Operation and Maintenance.		Yes, before September 15, 2020. No, on or after September 15, 2020.	See § 63.2840(g) for general duty requirement
§ 63.6(e)(1)(ii)	Operation and Maintenance.	Requirement to correct malfunctions as soon as practicable.	Yes, before September 15, 2020]. No, on or after September 15, 2020.	See § 63.2840(g) for general duty requirement.
§ 63.6(e)(3)(i) through (e)(3)(ii) and § 63.6(e)(3)(v) through (vii).	Operation and maintenance requirements.		Yes, before September 15, 2020.	Minimize emissions to the extent practicable. On or after September 15, 2020, see § 63.2840(g) for general duty requirement.
§ 63.6(e)(3)(iii)	Operation and maintenance requirements.		No	Minimize emissions to the extent practicable. On or after September 15, 2020, see § 63.2840(g) for general duty requirement.
§ 63.6(e)(3)(iv)	Operation and maintenance requirements.		No	Report SSM and in accordance with § 63.2861(c) and (d).

TABLE 1 TO § 63.2870—APPLICABILITY OF 40 CFR PART 63, SUBPART A, TO 40 CFR, PART 63, SUBPART GGGG—Continued

General provisions citation	Subject of citation	Brief description of requirement	Applies to subpart	Explanation
§ 63.6(e)(3)(viii)	Operation and maintenance requirements.		Yes, before September 15, 2020. No, on or after September 15, 2020.	Except, before September 15, 2020, report each revision to your SSM plan in accordance with § 63.2861(c) rather than § 63.10(d)(5) as required under § 63.6(e)(3)(viii).
§ 63.6(e)(3)(ix)	Title V permit		Yes, before September 15, 2020. No, on or after September 15, 2020.	
§ 63.6(f)(1)	Compliance with nonopacity emission standards except during SSM.	Comply with emission standards at all times except during SSM.	Yes, before September 15, 2020. No, on or after September 15, 2020.	
§ 63.6(f)(2)–(3)	Methods for Determining Compliance.		Yes.	
§ 63.6(g)	Use of an Alternative Standard.		Yes.	
§ 63.6(h)	Opacity/Visible emission (VE) standards.		No	Subpart GGGG has no opacity or VE standards.
§ 63.6(i)	Compliance extension.	Procedures and criteria for responsible agency to grant compliance extension.	Yes..	
§ 63.6(j)	Presidential compliance exemption.	President may exempt source category from requirement to comply with subpart.	Yes..	
§ 63.7(e)(1)	Performance testing requirements.	Representative conditions for performance test.	Yes, before September 15, 2020. No, on or after September 15, 2020.	See § 63.2853(a)(5)(i)(A) for performance testing requirements.
§ 63.7(e)(2)–(4), (f), (g), and (h).	Performance testing requirements.	Schedule, conditions, notifications and procedures.	Yes	Subpart GGGG requires performance testing only if the source applies additional control that destroys solvent. Section 63.2850(a)(6) requires sources to follow the performance testing guidelines of the General Provisions if a control is added.
§ 63.8	Monitoring requirements.		No	Subpart GGGG does not require monitoring other than as specified therein.
§ 63.9	Notification requirements.	Applicability and state delegation.	Yes	Except for subsections of § 63.9 as listed below.
§ 63.9(b)(2)	Notification requirements.	Initial notification requirements for existing sources.	No	Section 63.2860(a) of subpart GGGG specifies the requirements of the initial notification for existing sources.
§ 63.9(b)(3)–(5)	Notification requirements.	Notification requirement for certain new/reconstructed sources.	Yes	Except the information requirements differ as described in § 63.2860(b) of subpart GGGG.
§ 63.9(e)	Notification of performance test.	Notify responsible agency 60 days ahead.	Yes	Applies only if performance testing is performed.
§ 63.9(f)	Notification of VE/opacity observations.	Notify responsible agency 30 days ahead.	No	Subpart GGGG has no opacity or VE standards.
§ 63.9(g)	Additional notifications when using a continuous monitoring system (CMS).	Notification of performance evaluation; Notification using COMS data; notification that exceeded criterion for relative accuracy.	No	Subpart GGGG has no CMS requirements.

TABLE 1 TO § 63.2870—APPLICABILITY OF 40 CFR PART 63, SUBPART A, TO 40 CFR, PART 63, SUBPART GGGG—Continued

General provisions citation	Subject of citation	Brief description of requirement	Applies to subpart	Explanation
§ 63.9(h)	Notification of compliance status.	Contents	No	Section 63.2860(d) of subpart GGGG specifies requirements for the notification of compliance status.
§ 63.10	Recordkeeping/reporting.	Schedule for reporting, record storage.	Yes	Except for subsections of § 63.10 as listed below.
§ 63.10(b)(2)(i)	Recordkeeping	Record SSM event	Yes, before September 15, 2020. No, on or after September 15, 2020.	Before September 15, 2020, applicable to periods when sources must implement their SSM plan as specified in subpart GGGG. On or after September 15, 2020, meet the requirements of § 63.2862(f).
§ 63.10(b)(2)(ii)–(iii)	Recordkeeping	Malfunction of air pollution equipment.	No	Before September 15, 2020, applies only if air pollution control equipment has been added to the process and is necessary for the source to meet the emission limit. On or after September 15, 2020, meet the requirements of § 63.2862(g).
§ 63.10(b)(2)(iv)–(v)	Recordkeeping	SSM recordkeeping	Yes, before September 15, 2020. No, on or after September 15, 2020.	
§ 63.10(b)(2)(vi)	Recordkeeping	CMS recordkeeping	No	Subpart GGGG has no CMS requirements.
§ 63.10(b)(2)(viii)–(ix)	Recordkeeping	Conditions of performance test.	Yes	Applies only if performance tests are performed. Subpart GGGG does not have any CMS opacity or VE observation requirements.
§ 63.10(b)(2)(x)–(xii)	Recordkeeping	CMS, performance testing, and opacity and VE observations recordkeeping.	No	Subpart GGGG does not require CMS.
§ 63.10(c)	Recordkeeping	Additional CMS recordkeeping.	No	Subpart GGGG does not require CMS.
§ 63.10(d)(2)	Reporting	Reporting performance test results.	Yes	Applies only if performance testing is performed.
§ 63.10(d)(3)	Reporting	Reporting opacity or VE observations.	No	Subpart GGGG has no opacity or VE standards.
§ 63.10(d)(4)	Reporting	Progress reports	Yes	Applies only if a condition of compliance extension exists.
§ 63.10(d)(5)	Reporting	SSM reporting	No	Section 63.2861(c) and (d) specify SSM reporting requirements.
§ 63.10(e)	Reporting	Additional CMS reports.	No	Subpart GGGG does not require CMS.
§ 63.11	Control device requirements.	Requirements for flares.	Yes	Applies only if your source uses a flare to control solvent emissions. Subpart GGGG does not require flares.
§ 63.12	State authority and delegations.	State authority to enforce standards.	Yes.	
§ 63.13	State/regional addresses.	Addresses where reports, notifications, and requests are sent.	Yes.	
§ 63.14	Incorporation by reference.	Test methods incorporated by reference.	Yes.	
§ 63.15	Availability of information and confidentiality.	Public and confidential information.	Yes.	

■ 12. Section 63.2872 is amended in paragraph (c) by:

■ a. Revising the definitions for ''Compliance ratio'', ''Hazardous air pollutant (HAP)'', ''Initial startup period'', and ''Malfunction period'';

■ b. Adding a definition in alphabetical order for ''Nonoperating month''; and

■ c. Revising the definitions of ''Normal operating period'' and ''Operating month''.

The revisions and addition read as follows:

§ 63.2872 What definitions apply to this subpart?

* * * * *

Compliance ratio means a ratio of the actual HAP loss in gallons from the previous 12 operating months to an allowable HAP loss in gallons, which is determined by using oilseed solvent loss factors in Table 1 of § 63.2840, the weighted average volume fraction of HAP in solvent received for the previous 12 operating months, and the tons of each type of listed oilseed processed in the previous 12 operating months. Months during which no listed oilseed is processed, or months during which the § 63.2850(c)(2) or (d)(2) initial startup period or, before September 15, 2020, the § 63.2850(e)(2) malfunction period applies, are excluded from this calculation. Equation 2 of § 63.2840 is used to calculate this value. If the value is less than or equal to 1.00, the source is in compliance. If the value is greater than 1.00, the source is deviating from compliance.

* * * * *

Hazardous air pollutant (HAP) means any substance or mixture of substances listed as a hazardous air pollutant under section 112(b) of the Clean Air Act.

* * * * *

Initial startup period means a period of time from the initial startup date of a new, reconstructed, or significantly modified source, for which you choose to operate the source under an initial startup period subject to § 63.2850(c)(2) or (d)(2), until the date your source operates for 15 consecutive days at or above 90 percent of the nominal design rate of the extractor or at or above 90 percent of the permitted production rate for your source. The initial startup period following initial startup of a new or reconstructed source may not exceed 6 calendar months. The initial startup period following a significant modification may not exceed 3 calendar months. Solvent and oilseed inventory information recorded during the initial startup period is excluded from use in any compliance ratio determinations.

* * * * *

Malfunction period means a period of time between the beginning and end of a process malfunction and the time reasonably necessary for a source to correct the malfunction for which you choose to operate the source under a malfunction period subject to § 63.2850(e)(2). This period may include the duration of an unscheduled process shutdown, continued operation during a malfunction, or the subsequent process startup after a shutdown resulting from a malfunction. During a malfunction period, a source complies with the standards by minimizing HAP emissions to the extent practicable. Therefore, solvent and oilseed inventory information recorded during a malfunction period is excluded from use in any compliance ratio determinations.

* * * * *

Nonoperating month means any entire calendar or accounting month in which a source processes no agricultural product.

Nonoperating period means any period of time in which a source processes no agricultural product. This operating status does not apply during any period in which the source operates under an initial startup period as described in § 63.2850(c)(2) or (d)(2), or, before September 15, 2020, a malfunction period as described in § 63.2850(e)(2).

Normal operating period or *normal operation* means any period of time in which a source processes a listed oilseed that is not categorized as an initial startup period as described in § 63.2850(c)(2) or (d)(2), or, before September 15, 2020, a malfunction period as described in § 63.2850(e)(2). At the beginning and ending dates of a normal operating period, solvent and oilseed inventory information is recorded and included in the compliance ratio determination.

* * * * *

Operating month means any calendar or accounting month in which a source processes any quantity of listed oilseed, excluding any entire calendar or accounting month in which the source operated under an initial startup period as described in § 63.2850(c)(2) or (d)(2), or, before September 15, 2020, a malfunction period as described in § 63.2850(e)(2). An operating month may include time intervals characterized by several types of operating status. However, an operating month must have at least one normal operating period.

* * * * *

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Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 1141

Tobacco Products; Required Warnings for Cigarette Packages and Advertisements; Required Warnings for Cigarette Packages and Advertisements: Small Entity Compliance Guide; Guidance for Industry; Availability; Final Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1141

[Docket No. FDA–2019–N–3065]

RIN 0910–AI39

Tobacco Products; Required Warnings for Cigarette Packages and Advertisements

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing a final rule to establish new cigarette health warnings for cigarette packages and advertisements. The final rule implements a provision of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) that requires FDA to issue regulations requiring color graphics depicting the negative health consequences of smoking to accompany new textual warning label statements. The Tobacco Control Act amends the Federal Cigarette Labeling and Advertising Act (FCLAA) of 1965 to require each cigarette package and advertisement to bear one of the new required warnings. The final rule specifies the 11 new textual warning label statements and accompanying color graphics. FDA is taking this action to promote greater public understanding of the negative health consequences of cigarette smoking.

DATES: This rule is effective June 18, 2021. The incorporation by reference of a certain publication listed in the rule is approved by the Director of the Federal Register as of June 18, 2021.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of the final rule into the ''Search'' box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

With regard to the final rule: Courtney Smith, Office of Regulations, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, *AskCTPRegulations@fda.hhs.gov.*

With regard to the information collection: Daniel Gittleson, Office of Regulations, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

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I. Executive Summary

A. Purpose of the Final Rule

The final rule establishes new required warnings for cigarette packages and advertisements. These new cigarette health warnings consist of textual warning statements accompanied by color graphics depicting the negative health consequences of cigarette smoking.[1]

Cigarette smoking remains the leading cause of preventable disease and death in the United States and is responsible for more than 480,000 deaths per year. Smoking causes more deaths each year than human immunodeficiency virus, illegal drug use, alcohol use, motor vehicle injuries, and firearm-related incidents combined. In issuing the final rule, FDA determined that the public holds misperceptions about the health risks caused by smoking and that textual warning statements focused on less-known health consequences of smoking paired with concordant color graphics will promote greater public understanding of the risks associated with cigarette smoking, especially given that the existing Surgeon General's warnings currently used in the United States go unnoticed and are effectively ''invisible.'' FDA has determined that the required new cigarette health warnings will advance the Government's interest in promoting greater public understanding of the negative health consequences of cigarette smoking.

B. Summary of the Major Provisions of the Final Rule

The final rule establishes new required warnings to appear on cigarette packages and in cigarette advertisements. The rule implements a provision of the Tobacco Control Act that requires FDA to issue regulations requiring color graphics depicting the negative health consequences of smoking to accompany new textual warning statements. The Tobacco Control Act amends the FCLAA to require each cigarette package and advertisement to bear one of the new required warnings. These new cigarette health warnings consist of textual warning statements accompanied by color graphics, in the form of concordant photorealistic images, depicting the negative health consequences of cigarette smoking. As required by section 4 of the FCLAA, the new cigarette health warnings must appear prominently on packages and in advertisements, occupying the top 50 percent of the area of the front and rear panels of cigarette packages and at least 20 percent of the area at the top of cigarette advertisements.

In addition, as required under the FCLAA, the final rule establishes marketing requirements that include the

[1] For the purposes of discussion throughout this document, FDA uses the terms ''cigarette health warnings'' to refer to the required warnings and ''textual warning statements'' to refer to the textual warning label statements.

random and equal display and distribution of the required warnings for cigarette packages and quarterly rotation of the required warnings for cigarette advertisements. A tobacco product manufacturer, distributor, or retailer is required to submit a plan for the random and equal display and distribution of the required warnings on packages and the quarterly rotation in advertisements for approval by FDA. In addition, each tobacco product manufacturer that is required to randomly and equally display and distribute required warnings on packaging and quarterly rotate required warnings in advertisements, in accordance with an FDA-approved plan, also must maintain a copy of the FDA-approved plan and make the plan available for inspection and copying by officers and employees of FDA.

FDA developed the new cigarette health warnings included in the final rule through a science-based, iterative research process. The required warnings will promote greater public understanding of the negative health consequences of cigarette smoking.

C. Legal Authority

The final rule is being issued in accordance with sections 201 and 202 of the Tobacco Control Act (Pub. L. 111–31), which amend section 4 of the FCLAA (15 U.S.C. 1333). The final rule is also being issued based upon FDA's authorities related to misbranded tobacco products under sections 903 (21 U.S.C. 387c); FDA's authorities related to records and reports under section 909 (21 U.S.C. 387i); and FDA's rulemaking and inspection authorities under sections 701 (21 U.S.C. 371), 704 (21 U.S.C. 374), and 905(g) (21 U.S.C. 387e(g)) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

D. Costs and Benefits

This final rule requires that new cigarette health warnings, each comprising a textual warning statement paired with an accompanying color graphic, appear on cigarette packages and in cigarette advertisements. The final rule further requires that, for cigarette packages, these required warnings be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product, and be randomly and equally distributed throughout the United States in accordance with a plan approved by the FDA. The final rule also requires that, for cigarette advertisements, the required warnings be rotated quarterly in alternating sequences in advertisements for each brand of cigarettes in accordance with a plan approved by FDA. The final new cigarette health warnings will promote greater public understanding of the negative health consequences of cigarette smoking by presenting information about the health risks of smoking to smokers and nonsmokers in a format that helps people better understand these consequences. We describe economic benefits qualitatively. The cost of this final rule consists of initial and recurring labeling costs associated with changing cigarette labels to accommodate the new cigarette health warnings, design and operation costs associated with the random and equal display and distribution of the required warnings for cigarette packages and quarterly rotations of the required warnings for cigarette advertisements, advertising-related costs, and costs associated with government administration and enforcement of the rule. We estimate that, at the mean, the present value of the costs of this final rule is about $1.6 billion using a three percent discount rate and roughly $1.2 billion using a seven percent discount rate (2018$). If the information provided by the cigarette health warning on each cigarette package were valued at about $0.01 (for every pack sold annually nationwide), then the benefits that would be generated by the final rule would equal or exceed the estimated annual costs. This per-pack estimate provides one way to estimate the value the public would need to receive from the information provided on the cigarette health warnings in order to break even with the costs of the rule and is equivalent to 0.2 percent of the average cost of a pack of cigarettes, based on a national average cost of $6.27 per pack.[2]

II. Table of Abbreviations/Commonly Used Acronyms in This Document

Abbreviation/acronym	What it means
APA	Administrative Procedure Act.
CABG	Coronary artery bypass grafting.
CDC	Centers for Disease Control and Prevention.
COPD	Chronic obstructive pulmonary disease.
CVD	Cardiovascular disease.
D.C. Cir.	United States Court of Appeals for the District of Columbia Circuit.
EO	Executive Order.
EPA	Environmental Protection Agency.
EPS	Encapsulated PostScript.
FCLAA	Federal Cigarette Labeling and Advertising Act.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FDA	Food and Drug Administration or Agency.
FR	Federal Register.
HHS	U.S. Department of Health and Human Services.
NARA	National Archives and Records Administration.
NIFLA	Nat'l Inst. of Family and Life Advocates.
NSDUH	National Survey on Drug Use and Health.
OMB	Office of Management and Budget.
PAD	Peripheral arterial disease.
PATH	Population Assessment of Tobacco and Health.
PCI	Percutaneous coronary interventions.
PDF	Portable document format.
PMTA	Premarket tobacco product application.

[2] FDA's own analyses and calculations are based in part on data reported by Nielsen through its RMS service for the cigarettes category for the 11-week period ending March 23, 2019, for the total United States market and Convenience Stores and Expanded All Outlets Combined (xAOC) channels. Copyright © 2018, The Nielsen Company. The conclusions drawn from the Nielsen data are those of the FDA and do not reflect the views of Nielsen. Nielsen is not responsible for and had no role in and was not involved in analyzing and preparing the results reported herein. Nielsen RMS data consist of weekly purchase and pricing data generated from participating retail store point-of-sale systems in all U.S. markets. See *http://www.nielsen.com/us/en.html* for more information.

Abbreviation/acronym	What it means
PVD	Peripheral vascular disease.
SAMHSA	Substance Abuse and Mental Health Services Administration.
SES	Socioeconomic status.
TCA statements	Textual warning statements specified in section 4(a)(1) of the FCLAA.
TTB	Alcohol and Tobacco Tax and Trade Bureau.
WHO	World Health Organization.

III. Background

A. Introduction

To help inform consumers of the potential hazards of cigarette smoking, Congress passed the FCLAA that required that a printed text-only warning appear on cigarette packages (Pub. L. 89–92). The 1965 warning requirement was modified by later amendments to the FCLAA, including the Comprehensive Smoking Education Act of 1984 (Pub. L. 98–474), which extended the warning requirement to cigarette advertising and updated the one warning to four warnings, frequently referred to as the Surgeon General's warnings.

The FCLAA has required the inclusion of text-only warnings on cigarette packages and in cigarette advertisements for many years. As discussed in detail in the proposed rule (84 FR 42754, August 16, 2019) (hereinafter referred to as the proposed rule), there is considerable evidence that the Surgeon General's warnings go largely unnoticed and unconsidered by both smokers and nonsmokers (Ref. 1 at p. 291; see also section V of the proposed rule). These warnings, which have not changed in 35 years, have been described as ''invisible'' (Ref. 2) and fail to convey relevant information in an effective way (Ref. 1 at p. 291). The Surgeon General's warnings also do not include any color graphics.

In 2009, in enacting the Tobacco Control Act, Congress further amended the FCLAA and directed FDA to issue new cigarette health warnings that would include a graphic component depicting the negative health consequences of smoking to accompany the new textual warnings (section 201 of the Tobacco Control Act). In enacting this legislation, Congress also provided that FDA may adjust the warnings if FDA found that such a change would promote greater public understanding of the risks associated with the use of tobacco products (section 202 of the Tobacco Control Act).

As discussed in the proposed rule, the health risks associated with cigarette smoking are significant. In developing new cigarette health warnings for the final rule, FDA carefully examined the scientific literature, including the 2014 Surgeon General's Report (Ref. 3), which identified 11 more health conditions that have been established to have sufficient evidence to infer a causal link to cigarette smoking—the highest level of evidence of causal inferences from the criteria applied in the Surgeon General's Reports. Those health conditions examined in the 2014 Surgeon General's Report are in addition to the more than 40 unique health consequences already classified in previous Surgeon General's Reports as being caused by smoking and exposure to secondhand smoke. Additional findings in the scientific literature demonstrate that the U.S. public—including youth and adults, smokers and nonsmokers—holds misperceptions about the health risks caused by smoking (Refs. 4–10). Through its review of the scientific literature, as well as the Agency's science-based, iterative research and development process (see section VI of the proposed rule), FDA determined that having warning statements focused on less-known health consequences of smoking accompanied by photorealistic images would promote greater public understanding of the risks associated with cigarette smoking, especially given the unnoticed and ''invisible'' 1984 Surgeon General's warnings currently used in the United States.

Therefore, consistent with section 4 of the FCLAA (as amended by sections 201 and 202 of the Tobacco Control Act), we are finalizing a set of 11 required warnings, consisting of textual warning statements accompanied by concordant color graphics depicting the negative health consequences of smoking, to appear on cigarette packages and in cigarette advertisements. Specifically, we are replacing part 1141 to Title 21 of the Code of Federal Regulations (21 CFR part 1141), and the new part 1141 requires new cigarette health warnings on cigarette packages and in cigarette advertisements. As required by section 4 of the FCLAA, the new cigarette health warnings must appear prominently on packages and in advertisements, occupying the top 50 percent of the area of the front and rear panels of cigarette packages and at least 20 percent of the area at the top of cigarette advertisements.

As described in the preamble to the proposed rule and in the final rule, FDA has determined that the new required cigarette health warnings will advance the Government's interest in promoting greater public understanding of the negative health consequences of cigarette smoking.

On August 16, 2019, FDA issued a proposed rule to establish new required cigarette health warnings for cigarette packages and advertisements. These proposed cigarette health warnings consisted of a set of textual warning statements to be accompanied by concordant color graphics depicting the negative health consequences of smoking. FDA proposed to take this action to promote greater public understanding of the negative health consequences of cigarette smoking as directed by sections 201 and 202 of the Tobacco Control Act (amending section 4 of the FCLAA). FDA received about 300 comments to the docket for the proposed rule. Comments were received from cigarette manufacturers, retailers and retailer organizations, representatives of tribes/tribal organizations, health professionals and researchers, public health or other advocacy groups, academics, State and local public health agencies, medical organizations, individual consumers, and other submitters. These comments are summarized and responded to in the relevant sections of this document. Similar comments are grouped together by the topics discussed or the particular portions of the proposed rule or codified language to which they refer.

To make it easier to identify comments and FDA's responses, the word ''Comment,'' in parenthesis, appears before the comment's description, and the word ''Response,'' in parenthesis, appears before FDA's response. Each comment is numbered to help distinguish among different comments, and the number assigned is purely for organizational purposes and does not signify value or importance. Similar comments are grouped together under the same comment number. In addition to the comments specific to this rulemaking that we address in the following sections, we received many general comments expressing support or opposition to the rule and separate

provisions within the rule. These comments express broad policy views and do not address specific points related to this rulemaking. Therefore, these general comments do not require a response. The remaining comments, as well as FDA's responses, are included in this document.

B. Incorporation by Reference

FDA is incorporating by reference ''Required Cigarette Health Warnings, 2020,'' which was approved by the Office of the Federal Register. You may obtain a free copy of the material from FDA's website, located at *https://www.fda.gov/cigarette-warning-files;* the Docket at *https://www.regulations.gov;* or from the Food and Drug Administration, Center for Tobacco Products, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, email: *cigarettewarningfiles@fda.hhs.gov.*

The material incorporated by reference, entitled ''Required Cigarette Health Warnings, 2020,'' includes the required warnings (comprising a textual warning statement, as specified in § 1141.10(a), and its accompanying color graphic) in different layouts based on the size and aspect ratio of the display area where the required warning must appear (*i.e.,* on cigarette packages, in cigarette advertisements). We have included an electronic portable document format (PDF) file containing all the required warnings as a reference in the docket for the final rule (Ref. 11). FDA is also making this material available on its website at *https://www.fda.gov/cigarette-warning-files.*

FDA recognizes that adaptations to the required warnings may be needed to avoid technical implementation issues due to the varying features, formats, and sizes of cigarette packages and advertisements. To help prevent distortion of the image and text and to minimize the need for adaptation, FDA has created electronic, layered design files, built as Encapsulated PostScript (.eps) files, in different formats and aspect ratios designed to fit packaging and advertising of various shapes and sizes. FDA is not requiring the use of these .eps files, but rather we are providing the files as a resource to assist regulated entities implement part 1141. In addition to the material incorporated by reference and the .eps files, FDA is making available a technical specifications document that includes information on how to access, select, use, and adapt the appropriate .eps file based on the size and aspect ratio of the display area where the required warning must appear. These .eps files and technical specifications are also available on FDA's website at *https://www.fda.gov/cigarette-warning-files.*

IV. Legal Authority

A. Summary of Legal Authority

As set forth in the preamble to the proposed rule, the Tobacco Control Act amends the FD&C Act and provides FDA with the authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors. Section 201 of the Tobacco Control Act amends section 4 of the FCLAA to require that nine new health warning statements appear on cigarette packages and in cigarette advertisements and directs the Secretary of the Department of Health and Human Services [3] to ''issue regulations that require color graphics depicting the negative health consequences of smoking'' to accompany the nine new health warning statements. Congress also provided that the provision requiring the new health warning statements would not become effective until after the graphic label rulemaking was completed. Under section 201 of the Tobacco Control Act, in a subsection entitled ''Graphic Label Statements,'' FDA may adjust the type size, text, and format of the cigarette health warnings as FDA determines appropriate so that both the color graphics and the accompanying textual warning statements are clear, conspicuous, and legible and appear within the specified area (15 U.S.C. 1333(d)).

Section 202(b) of the Tobacco Control Act, in a subsection entitled ''Change in Required Statements,'' also amends section 4 of the FCLAA to add a new subsection that permits FDA, through a rulemaking, to adjust the format, type size, color graphics, and text of any of the label requirements, or establish the format, type size, and text of any other disclosures required under the FD&C Act, if such a change would promote greater public understanding of the risks associated with the use of tobacco products (15 U.S.C. 1333(d)).[4] Such adjustments, including adjustments to the text of some of the warning statements and to the number of required warnings, were included as part of the proposed rule.

These requirements are supplemented by the FD&C Act's misbranding provisions, which require that product labeling and advertising include required warnings (section 903). Under section 701(a) of the FD&C Act, FDA has authority to issue regulations for the efficient enforcement of the FD&C Act, and sections 704 and 905(g) provide FDA with general inspection authority.

Section 909 of the FD&C Act authorizes FDA to require tobacco product manufacturers to establish and maintain records, make reports, and provide such information as the Agency may by regulation reasonably require to ensure that a tobacco product is not adulterated or misbranded and to otherwise protect public health.

While FDA did not receive comments on many of these authorities, FDA did receive comments regarding our authority to require more than nine warning label statements and to adjust the text, as well as comments related to the Administrative Procedure Act (APA) and the constitutionality of the required warnings. These comments are summarized and responded to in the following paragraphs. Multiple comments are often summarized together for convenience. Comment numbers are assigned to facilitate later reference; they do not indicate importance or the sequence in which comments were received.

B. Comments Regarding Legal Authority

(Comment 1) FDA received several comments, including comments from cigarette manufacturers and a retail organization, disputing FDA's authority to adjust the text of the warning label statements, to propose textual warning statements other than the nine warnings included in section 201 of the Tobacco Control Act (amending section 4 of the FCLAA), and to require more than nine warning label statements. These comments argue that section 202(b) only permits FDA to adjust the format and type size for the label statement, which does not include rewriting and replacing the Tobacco Control Act warning label statements. Instead, FDA should have proposed warnings that used only the text statements that Congress set out in section 201 of the Tobacco Control Act.

(Response 1) FDA disagrees with these comments. When Congress passed the Tobacco Control Act, Congress also amended the FCLAA to give the Secretary more specific authority to

[3] The Secretary has delegated this authority to FDA. For the purposes of discussion throughout this document, FDA uses ''FDA'' when discussing this authority.

[4] Section 201(a) of the Tobacco Control Act amends section 4 of the FCLAA to add a new subsection (d), ''Graphic Label Statements,'' which is codified at 15 U.S.C. 1333(d). Section 202(b) of the Tobacco Control Act amends section 4 of the FCLAA to also add a new subsection (d), ''Change in Required Statements,'' which is also codified at 15 U.S.C. 1333(d). Both provisions of the Tobacco Control Act are correctly codified as ''15 U.S.C. 1333(d).'' To reduce confusion, this document refers to them, respectively, as section 201 and section 202(b).

adjust and revise required cigarette warnings. This new authority includes two separate provisions authorizing FDA to revise aspects of the warning statements:

- Section 201 of the Tobacco Control Act, which provides that the Secretary ''may adjust the type size, text and format of the label statements *specified in [FCLAA] subsections 4(a)(2) and 4(b)(2)* as the Secretary determines appropriate so that both the graphics and accompanying label statements are clear, conspicuous, legible and appear within the specified area;'' and
- Section 202(b), which permits the Secretary, through a rulemaking, to ''adjust the format, type size, color graphics, and text of any of the label requirements . . . if the Secretary finds that such a change would promote greater public understanding of the risks associated with the use of tobacco products.'' (Emphasis added.)

It is significant that section 201 cross-references subsections (a)(2) and (b)(2); subsection (a)(2) addresses ''Placement; typography; etc.'' for the ''label statement[s] required by paragraph [(a)(1)]'' for package labels, and subsection (b)(2) addresses the ''Typography, etc.'' of the ''label statement[s] required by subsection (a)'' for cigarette advertising. Thus, the adjustments authorized by section 201 focus on placement, typography, clarity, conspicuousness, and legibility—changes that go to the visual presentation of cigarette warnings. By contrast, section 202(b) gives the Secretary broader authority to ''adjust the format, type, size, color graphics, and text of any of the label *requirements*'' (emphasis added). Section 202(b)'s reference to ''label requirements'' is also significant; at minimum, it refers to and sweeps in the entirety of FCLAA subsection 4(a), which is entitled ''Label Requirements.'' Also importantly, section 202(b) allows its more sweeping adjustments only upon a finding that ''such a change would promote greater public understanding of the risks'' of smoking.

The adjustments permitted by section 202(b) therefore differ from those permitted by section 201 in that:

(1) section 202(b) authorizes adjustments to ''any of the label *requirements*'' of FCLAA subsection 4(a), rather than just adjustments to the ''type size, text and format'' specified in FCLAA subsection 4(a)(2) (governing the placement, typography, etc., of the ''label statements'' on package labels) and (4)(b)(2) (governing the typography, etc., of the ''label statements'' in cigarette advertising);

(2) the relevant finding relates to promoting the public's understanding of the risks associated with the use of tobacco products rather than the visual clarity of the label statements; and

(3) section 202(b) explicitly requires rulemaking under 5 U.S.C. 553 for the adjustments it authorizes, while section 201 does not.

We therefore disagree with comments that argue that, under section 202(b), FDA may only adjust the typographic look of the warnings' text, not their substance. That assertion conflicts with the plain meaning of ''text,'' which, as comments concede, refers to both ''words and form,'' not merely the latter. The interpretation is also inconsistent with the difference in the predicate findings required for adjustments under sections 201 and 202(b): Visual clarity versus improving public understanding of risks. If Congress had meant section 202(b) to limit FDA to making adjustments to improve visual clarity, it would not have included a predicate finding that relates to the warnings' substance. Congress further indicated its intent to allow more substantive changes under section 202(b) by explicitly requiring rulemaking under 5 U.S.C. 553, while adjustments under section 201 are allowed simply upon the Secretary's determination.

Some comments argue that the term ''adjust'' precludes changes that would better be described by the term ''edit'' or ''revise.'' FDA disagrees. First, the title of section 202 of the Tobacco Control Act is ''Authority to *Revise* Cigarette Warning Label Statements'' (emphasis added). That title reflects Congress's intent to authorize FDA to revise the warning statements themselves, not merely make typographical changes. Second, section 202(b) includes the authority to adjust not only the text of the warnings but also non-textual items like ''format,'' ''type size,'' and ''color graphics''—''edit'' or ''revise'' would not as clearly encompass the types of changes associated with those items. It is therefore likely that Congress chose the term ''adjust'' as an umbrella term best suited to include the variety of changes authorized under section 202(b) of the Tobacco Control Act.

FDA also disagrees with the comments that asserted that Congress did not authorize FDA to adjust the number of warnings. As discussed below, it is far from clear that the number of warnings is in fact a statutory requirement. But even if it were, the statutory language does not speak directly to this issue, and FDA reasonably construes the statute to allow it to adjust the number of warnings. Section 202(b) of the Tobacco Control Act authorizes FDA to adjust the ''text of any of the label *requirements*'' if such a change would promote greater public understanding of the risks associated with the use of tobacco products—not just to adjust the ''types size, text and format of the label *statements*'' specified in subsections governing ''placement, typography, etc.'' so that both the graphics and the accompanying label statements are clear, conspicuous, legible, and appear within the specified area, as section 201 does (emphasis added).

As amended by the Tobacco Control Act, subsection 4(a) of the FCLAA, which identifies the ''label requirements'' that may be adjusted under section 202(b), does not provide a requirement as to how many warnings there must be. Nothing in the head of subsection 4(a)(1) refers to ''9 labels''; rather, it refers to ''one of the following labels.'' In addition, section 202(a) of the Tobacco Control Act amends the FCLAA's preemption provision, subsection 5(a) of the FCLAA, to provide that, ''Except to the extent the Secretary requires *additional* or different statements on any cigarette package by a regulation, . . . no statement relating to smoking and health, other than the statement required by section 4 of [the FCLAA, now amended by the Tobacco Control Act], shall be required on any cigarette package.'' FCLAA subsection 5(a), as amended by Tobacco Control Act section 202(a) (codified at 15 U.S.C. 1334(a)) (emphasis added). The reference to ''additional'' statements indicates that Congress did not consider nine warnings to be a fixed statutory requirement. In any event, by authorizing adjustments to the ''text of any of the label requirements,'' section 202(b) plainly contemplates that FDA may adjust the ''text'' of the label requirements within paragraph (1) of subsection 4(a) of the FCLAA (which is entitled ''Label Requirements''), precisely as this final rule does.

Even if FCLAA subsection 4(a)(1) required ''one of the following 9 labels,'' and not just ''one of the following labels,'' as it actually does, such a numeric requirement would still be among the FCLAA ''label requirements'' subject to being adjusted under section 202(b) of the Tobacco Control Act. FDA has determined that all 11 warnings that are part of this final rule will promote greater public understanding of the risks of cigarette smoking. FDA therefore may adjust the number of warnings through this rulemaking conducted under 5 U.S.C. 553.

(Comment 2) One comment states that FDA does not have the authority to

change the textual statements provided in the Tobacco Control Act without implementing them first.

(Response 2) FDA disagrees. Under section 202(b), FDA may, through a rulemaking, adjust the format, type size, color graphics, and text of any of the label requirements if the Secretary finds that such a change would promote greater public understanding of the risks associated with the use of tobacco products. Nothing in the language of section 202(b) of the Tobacco Control Act requires the Agency to first issue warnings with the Tobacco Control Act statements, and then wait 15 months or more for such warnings to be implemented, before the Agency may embark on an effort to revise the warning statements. What the statute requires is that revisions to the textual warning statements specified in section 4(a)(1) of the FCLAA (''TCA statements'') be based on a finding that such a change would promote greater public understanding of the risks of smoking. Accordingly, in considering whether to revise the warnings, FDA designed and undertook a rigorous science-based, iterative research process specifically to assess whether new textual warning statements would promote greater public understanding of the risks associated with tobacco products compared to the warning statements provided in the Tobacco Control Act. As part of its research, FDA conducted a large (2,505 participants) quantitative consumer research study (OMB control number 0910–0848, ''Experimental Study on Warning Statements for Cigarette Graphic Health Warnings''). This first consumer research study evaluated new textual warnings statements compared to the warning statements provided in the Tobacco Control Act to determine if they would promote greater understanding of the risks of smoking. More details about the study methodology can be found in the study report included in the docket (Ref. 12). The results show that, with respect to the outcomes most predictive for demonstrating greater understanding of the risks of smoking—''new information'' and ''self-reported learning''—nearly all tested new textual warning statements performed significantly better than nearly all textual warning statements provided by the Tobacco Control Act. The results of this first consumer research study informed the selection of textual warning statements that FDA then paired with concordant images for testing in a final consumer research study (OMB control number 0910–0866, ''Experimental Study of Cigarette Warnings'') (see section VI for more discussion about FDA's approach to developing and testing cigarette health warnings). FDA has therefore complied with section 202(b) by including new textual warnings in the final rule only after finding that they will promote greater public understanding of the risks associated with smoking as compared to certain textual warnings in the Tobacco Control Act that are excluded from the final rule.

C. Comments Regarding First Amendment Considerations

FDA received comments from industry, retailers, public health organizations and coalitions, state and local governments, academia, and private citizens related to First Amendment considerations. Several comments from manufacturers, retail organizations, and private citizens assert that the required warnings violate the First Amendment of the United States Constitution under a variety of legal standards. Several other comments, including from public health organizations and state and local governments, state that the required warnings comport with First Amendment requirements.

1. Government's Interest

(Comment 3) Some comments suggest that the Government's interest in promoting greater public understanding of the negative health consequences of cigarette smoking is not substantial, and that, in any case, FDA's Population Assessment of Tobacco and Health (PATH) data and public health campaigns undermine that asserted interest. Related comments suggest that, under the Supreme Court's decision in *Nat'l Inst. of Family and Life Advocates (NIFLA)* v. *Becerra,* 138 S. Ct. 2361 (2018), the Government may not compel ''unjustified disclosures,'' such as disclosures that fail to address a harm that is potentially real and not purely hypothetical, or that fail to remedy the harm, *e.g.,* by telling people things they already know.

Other comments state that ''communicat[ing] health information to the public about the negative health effects of cigarettes'' is not the Government's interest, because the Tobacco Control Act identifies the Government's interest as reducing the number of youth and adults that use cigarettes. These comments assert that FDA should not proceed unless FDA demonstrates the new text and color graphics will reduce smoking rates. Similarly, other comments assert that, as with the 2011 final rule (76 FR 36628, June 22, 2011), FDA's ''true'' governmental interest is to reduce smoking and that FDA has not provided any evidence in support of that interest. Other comments generally support FDA's interest in promoting greater public understanding of the negative health consequences as a substantial Government interest that fully supports the rule.

(Response 3) FDA agrees with the comments that recognize that promoting greater public understanding of the negative health consequences of smoking is a substantial Government interest that fully supports the rule. Providing relevant, truthful, and non-misleading information to consumers in ways that promote greater public understanding provides consumers with a better opportunity to make informed choices. *See, e.g., Greater New Orleans Broad. Ass'n* v. *United States,* 527 U.S. 173, 184–85 (1999); Ref. 13 at 405 (''Disclosure requirements are based on the 'informational function' of commercial speech and the accepted understanding that it would be impossible for consumers to verify such information on their own. As a result, the U.S. regulatory landscape is replete with commercial disclosure requirements.'').

As the Sixth Circuit concluded, ''[t]here can be no doubt that the government has a significant interest in . . . warning the general public about the harms associated with the use of tobacco products.'' *Discount Tobacco City & Lottery, Inc.* v. *U.S.,* 674 F.3d 509, 519 (6th Cir. 2012). Cigarette smoking remains the primary cause of preventable disease and death in the United States. The magnitude of this public health crisis is compounded by the gaps in knowledge and misperceptions held by smokers and nonsmokers about the wide variety of negative health consequences caused by smoking.

Moreover, FDA's research confirms that the public continues to hold misperceptions about the health risks of smoking and is largely unaware of certain serious conditions caused by smoking (see section V.B; see also NPRM section V.A.3, 84 FR at 42761–62 (''There Remain Significant Gaps in Public Understanding About the Negative Health Consequences of Cigarette Smoking'')). Contrary to some comments' assertions, consumers suffer from a pervasive lack of knowledge about the negative health consequences of smoking, as both smokers and nonsmokers do not fully understand that smoking is causally linked to a wide variety of diseases and health conditions (see section V.B).

We disagree with comments that argue the public's knowledge of the general harms of cigarette smoking undercuts the need for these required warnings. As clearly demonstrated by the rulemaking record, both the harms of cigarette smoking thoroughly detailed in years of Surgeon General's reports, and the widespread public misperceptions about these harms, are very ''real not purely hypothetical.'' *NIFLA,* 138 S. Ct. at 2377.

Congress has long recognized and taken steps to address this information gap. As far back as 1965 when Congress first passed the FCLAA, it set forth the policy of a comprehensive warning program on cigarette packages and advertisements so that ''the public may be adequately informed'' about the dangers of cigarette smoking. FCLAA Section 2(1), codified at 15 U.S.C. 1331(1). When Congress amended the FCLAA with the Tobacco Control Act, it recognized that the current 1984 Surgeon General's warnings had become ''ineffective in providing adequate warnings about the dangers of tobacco products'' (Ref. 14 at 4). To that end, Congress mandated new cigarette warnings to be accompanied by color graphics and provided the Secretary with the authority to adjust such warning label requirements if ''such a change would promote greater public understanding of the risks associated with the use of tobacco products'' (section 202(b) of the Tobacco Control Act).

Under the framework set out in *Zauderer* v. *Office of Disciplinary Counsel,* 471 U.S. 626 (1985), which FDA believes is applicable here, a Government interest supporting factual disclosures need not be substantial. But even if a substantial interest were required, that standard is easily met for these required warnings. ''[T]here is no question that [the Government's] interest in ensuring the accuracy of commercial information in the marketplace is substantial.'' *Spirit Airlines, Inc.* v. *U.S. Dep't of Transp.,* 687 F.3d. 403, 415 (D.C. Cir. 2012). That interest is heightened when the information at issue concerns the health risks inherent in using a product. *See Posadas de Puerto Rico Assocs.* v. *Tourism Co. of Puerto Rico,* 478 U.S. 328, 341 (1986) (''[H]ealth, safety, and welfare constitute a 'substantial' governmental interest''); *CTIA-The Wireless Ass'n* v. *City of Berkeley,* 928 F.3d 832, 845 (9th Cir.) (''There is no question that protecting the health and safety of consumers is a substantial governmental interest.''), *cert. denied,* 205 L. Ed. 2d 387 (Dec. 9, 2019). As discussed in further detail in the preamble to the proposed rule, as well as in section VII below, the required warnings provide factual and accurate information about the products that are subject to them. The disclosure of factual and accurate information promotes greater consumer understanding about their choices in the marketplace. Because ''tobacco products are dangerous to health when used in the manner prescribed,'' *FDA* v. *Brown & Williamson Tobacco Corp.,* 529 U.S. 120, 135 (2000), the Government has a substantial interest in requiring disclosures providing factual and accurate information about the negative health consequences of such products to promote greater public, including consumer, understanding.

FDA also does not agree with comments asserting that the Agency's one true interest lies in reducing smoking rates. The comments cite to Congressional findings in the Tobacco Control Act, which indicate that Congress's purposes for the Tobacco Control Act *as a whole* include reducing the use of tobacco by minors in an effort to protect millions from suffering premature death due to tobacco-induced disease. However, with respect to the warning requirements for cigarettes, the statute itself is specific: The required warnings are to ''depict[] the negative health consequences of smoking'' and any changes to these label requirements are to ''promote greater public understanding of the risks associated with the use of tobacco products'' (sections 201 and 202 of the Tobacco Control Act).

2. *Zauderer*

In the proposed rule, FDA explained that this rule would be properly analyzed under the *Zauderer* standard, under which the Government may require the disclosure of factual and uncontroversial information in commercial marketing where the disclosure is justified by a governmental interest and does not unduly burden protected speech. FDA received many comments addressing the applicability of the First Amendment standard set out in *Zauderer.*

Some of the comments suggest that the required warnings FDA proposed cannot be upheld under *Zauderer* because they are not required to remediate any misleading commercial speech or disclose information about the terms under which services are available; do not provide purely factual and uncontroversial information; and are unjustified, unduly burdensome, and not reasonably related to a substantial Government interest. Other comments from public health organizations and academia support the required warnings as appropriate under the First Amendment and specifically under *Zauderer* because these are mandatory factual disclosures that convey valuable factual information to consumers.

a. Applicability of *Zauderer*

(Comment 4) Some comments argue that the proposed warnings should not be subject to evaluation under *Zauderer* because they are not being issued to address consumer deception.

(Response 4) FDA disagrees that *Zauderer* applies only to disclosures that seek to address consumer deception. The comments to the contrary highlight the ''preventing deception'' phrase at the end of this passage in *Zauderer:* ''we hold that an advertiser's rights are adequately protected as long as disclosure requirements are reasonably related to the State's interest in preventing deception of consumers.'' *Zauderer,* 471 U.S. at 651. But this passage merely references ''the State's interest'' in the particular case before the Court, which contended that advertisements without certain disclosures were ''false or deceptive.'' *Id.* at 633. The Court made no suggestion that its analysis was confined to mandatory disclosures that seek to prevent deception and no others.

The D.C. Circuit considered and rejected such a limited reading of *Zauderer* in *American Meat Institute* v. *U.S. Department of Agriculture,* 760 F.3d 18 (D.C. Cir. 2014) (en banc). In *American Meat,* a Department of Agriculture regulation implementing a federal statute required identification of the country of origin on the packaging of meat and meat products. *Id.* at 20. Examining the facts and language at issue in *Zauderer* and *Milavetz, Gallop & Milavetz, PA.* v. *United States,* 559 U.S. 229, 253 (2010), in which the Court repeated the ''preventing deception'' language, the D.C. Circuit held that *Zauderer* should not be read to apply only to cases where Government-compelled speech prevents or corrects deceptive speech. *Id.* at 22.

Other circuits addressing this issue have unanimously agreed. In 2001, the Second Circuit applied *Zauderer* and upheld a compelled disclosure supported by a substantial state interest in protecting human health and environment, ''intertwined with the goal of increasing consumer awareness of the presence of mercury in a variety of products,'' even though it was ''not intended to prevent 'consumer confusion or deception' per se.'' *National Electrical Manufacturers Association* v. *Sorrell,* 272 F.3d 104, 115

(2d Cir. 2001) (quoting *Zauderer*). *Accord, CTIA,* 928 F.3d at 844 (*cert. denied,* 205 L. Ed. 2d 387 (Dec. 9, 2019)) (government interest in furthering public health and safety is sufficient under *Zauderer* so long as it is substantial); *Discount Tobacco,* 674 F.3d at 556–58 (upholding federally required health warnings on cigarette packaging and in cigarette advertisements, citing *Sorrell*); *Pharm. Care Mgmt. Ass'n* v. *Rowe,* 429 F.3d 294, 310 n. 8 (1st Cir. 2005) (noting that the court had found no cases limiting application of the *Zauderer* compelled speech test to prevention or correction of deceptive advertising); *cf. Dwyer* v. *Cappell,* 762 F.3d 275, 281–82 (3d Cir. 2014) (describing but not relying on *Zauderer's* preventing-deception criterion). And nothing in *NIFLA* calls those precedents into doubt. *See Am. Bev. Ass'n* v. *City & City of San Francisco,* 916 F.3d 749, 756 (9th Cir. 2019) (en banc) (''*NIFLA* did not address, and a fortiori did not disapprove, the circuits' precedents . . ., which have unanimously held that *Zauderer* applies outside the context of misleading advertisements.'').

The required health warnings are in any event intended in part to correct consumer misperceptions regarding the risks presented by cigarettes, and thereby ''to dissipate the possibility of consumer confusion or deception.'' *Zauderer,* 471 U.S. at 651 (internal quotation marks omitted). There is a long history of deception concerning consumer health risks in the cigarette industry. The 2014 Surgeon General's Report provided a 50-year survey, and the second of its ten ''Major Conclusions'' was that ''[t]he tobacco epidemic was initiated and has been sustained by the aggressive strategies of the tobacco industry, which has deliberately misled the public on the risks of smoking cigarettes'' (Ref. 3 at 7). *See also United States* v. *Philip Morris USA Inc.,* 566 F.3d 1095 (D.C. Cir. 2009) (upholding racketeering, fraud, and conspiracy findings against the nation's major cigarette companies). Even if the largest players in the industry had not engaged in half a century of fraud, FDA's extensive evidence demonstrates that important consumer misperceptions regarding the nature and degree of the risks presented by these products persist. Therefore, FDA does not agree that *Zauderer* scrutiny is inapplicable here.

(Comment 5) At least one comment argues that the proposed warnings should not be subject to evaluation under *Zauderer* because the Supreme Court in *NIFLA* limited *Zauderer* to cases involving disclosures regarding the provision of services, not goods.

(Response 5) FDA does not agree *Zauderer* is limited to cases involving the provision of services. The Supreme Court in *NIFLA* ''d[id] not question the legality of health and safety warnings long considered permissible, or purely factual and uncontroversial disclosures about commercial *products.*'' 138 S. Ct. at 2376 (emphasis added). While the question presented in that case concerned *Zauderer's* application to services other than those provided by the speaker, *id.* at 2372, nothing in the opinion suggests that the Court intended to limit *Zauderer's* applicability to *services* to the exclusion of *products.*

b. Factual, Accurate, and Uncontroversial

(Comment 6) FDA received comments addressing the factualness and accuracy of the required warnings. Under *Zauderer,* these comments state, a compelled disclosure must be purely factual, and disclosure requirements that are intended to evoke an emotional response, shock the viewer into retaining information, or convey an ideological message about how consumers should behave do not qualify as purely factual. Many of these comments referred to the D.C. Circuit's 2012 decision striking down the pictorial cigarette warnings the Agency issued in 2011, *R.J. Reynolds Tobacco Co.* v. *FDA,* 696 F.3d 1205 (D.C. Cir. 2012). These comments generally imply that any pictorial cigarette warning cannot be factual because the point of the warnings is to force consumers to look at gruesome images that evoke feelings of shame and fear and to convey an ideological message turning cigarette packages and advertisements into mini-billboards for the Government's anti-smoking position. The comments also specifically suggest that the required warnings proposed by FDA are not purely factual because they contain what the commenters consider shocking and inflammatory images. The comments cite as examples the images of diseased feet with amputated toes, the head and neck tumor, and the lungs, which the comments say are intended to convey emotions of fear, shame, and disgust. The comments also contend that FDA's consumer studies confirm that the required warnings are not factual because the first quantitative consumer research study showed that many of the tested statements were perceived to be less believable than the Tobacco Control Act's warning statements, and in the final quantitative consumer study, eight of the proposed warnings were less likely to be ''perceived as factual'' than the Surgeon General's warnings.

FDA also received comments that the required warnings proposed by FDA are factual and accurate because the textual statements and accompanying photorealistic images depicting the health harm described or the effect of that harm are supported by a broad consensus of scientific research and U.S. Surgeon General's Reports. The comments point to FDA's final quantitative consumer research study showing that the new text warnings, paired with the accompanying images, provide new information that promotes greater public understanding of the negative health consequences of smoking. These comments also note that there is nothing in the administrative record that suggests the color images are intended to evoke an emotional response instead of illustrating the factual statements. The comments observe that, to the extent any information about actual negative health effects of smoking evokes emotion, that response does not make the information or images any less factual.

Some comments also suggest that the warnings do not provide purely factual and uncontroversial information but instead are misleading because they ''do not depict conditions as they are typically experienced by smokers and instead depict procedures or outcomes that are distinct from or extreme as compared to the written warning.'' Comments state that several of the images ''exaggerate the effects of the diseases they purport to represent, exaggerate the likelihood of those diseases caused by smoking, or offer a misleading portrayal of the treatment of those diseases.'' Other comments suggest that the required warnings proposed by FDA do not go far enough in visual depiction or textual statement, which results in misleading understatements of the negative health consequences of smoking. Some comments also state that FDA did not develop evidence that the required warnings convey factual information to consumers in a way that is not misleading and suggest the studies were not designed to do so. Comments suggest that the study designs did not evaluate whether any of the warnings FDA proposed conveyed accurate information, and that, for example, unlike FDA's draft recommendations with modified risk tobacco products, FDA failed to evaluate consumer understanding of absolute and relative risk.

(Response 6) FDA disagrees with those comments that suggest the visual depictions are not factual and accurate

based on their assertion that they are designed to evoke an emotional response, such as disgust, and agrees with those comments that say the images illustrate the factual and accurate textual statements with which they are paired. In developing the proposed images, FDA conducted a science-based, iterative research process to develop, test, and refine images that were factually accurate; that depicted common visual presentations of the health conditions and/or showed disease states and symptoms as they are typically experienced; that presented the health conditions in a realistic and objective format devoid of non-essential elements; and that study participants found were concordant with the statements on the same health conditions. To do this, FDA staff, including internal medical experts from a range of specialties, worked closely with a certified medical illustrator to develop high quality, factually accurate photorealistic images (see section VI of the proposed rule, 84 FR at 42765–66, 42770–71).

While there is little guidance from the courts with respect to what constitutes factual and accurate with respect to images for purposes of *Zauderer* scrutiny, some comments have noted that the majority of the resulting images now being included in the final warnings match up with examples of potential factual disclosures given by the Sixth Circuit in *Discount Tobacco,* 674 F.3d 509. In *Discount Tobacco,* the Sixth Circuit provided a non-exhaustive list of the types of images that could pass muster under *Zauderer* as factual and uncontroversial accompanying cigarette warnings. These include, for example, ''a picture or drawing of the internal anatomy of a person suffering from a smoking-related medical condition'' (images in the required warnings include a diseased lung); a ''picture or drawing of a person suffering from a smoking-related medical condition'' (images in the required warnings include persons suffering from cataracts, reduced blood flow, heart disease, erectile dysfunction, respiratory problems, head and neck cancer, and chronic obstructive pulmonary disease (COPD)); or ''pictures consisting of text and simple graphic images'' (images in the required warnings include an underweight baby on a scale, a urine specimen cup, and a blood glucose monitor). *Discount Tobacco,* 674 F.3d at 559. As the Sixth Circuit noted, medical students look at such pictures or drawings to learn about medical conditions and biological systems because they are factual. *Id.* The images included in the warnings reflect precisely that type of factual content.

FDA also carefully considered the D.C. Circuit's conclusions regarding the Agency's 2011 cigarette warning final rule, including the court's statements criticizing those images as having been designed ''to evoke an emotional response'' with ''inflammatory images and the provocatively-named hotline.'' *R.J. Reynolds,* 696 F.3d at 1216 (referencing ''1–800–QUIT–NOW'' hotline). The Court further found that ''many'' of the images ''could be misinterpreted by consumers.'' *Id.* (stating that an ''image of a man smoking through a tracheotomy hole might be misinterpreted as suggesting that such a procedure is a common consequence of smoking,'' rather than symbolize the addictive nature of cigarettes, as FDA contended—in other words, consumers might not find the images concordant with their accompanying text statements). The D.C. Circuit additionally found that ''many'' of the images did ''not convey *any* warning information at all.'' *Id.* (referencing images of a woman crying, a small child, and a man wearing a T-shirt emblazoned with the words ''I QUIT''). FDA has addressed those criticisms in several ways. FDA used a certified medical illustrator to design images that depicted common visual presentations of the health conditions and/or showed disease states and symptoms as they are typically experienced, and that present the health conditions in a realistic and objective format devoid of non-essential elements. FDA used different criteria to select and study the images and warnings for this rule than it did in the 2011 rulemaking. FDA developed the current warnings by designing and testing potential images, potential text statements, and potential pairings of text statements with images multiple times with different groups of consumers to ensure—and be able to demonstrate—that they are unambiguous and unlikely to be misinterpreted or misunderstood (in contrast to *Reynolds'* concern that consumers might misunderstand the image of a man smoking through his tracheotomy hole), and that they do convey warning information (in contrast to *Reynolds'* concerns that images of a woman crying, a small child, and a man wearing an ''I QUIT'' T-shirt provided no information at all).

Some may argue that, because the warnings will promote greater public understanding about the very real, serious, and sometimes deadly outcomes of cigarette smoking, their factually accurate content may evoke subjective, emotional responses from some consumers based on their personal history and personality characteristics. In general, the possibility that factual content may evoke an emotional reaction does not render the content less factual. In this context, an emotional reaction on the part of some individuals would not render the warnings or the health information they convey ''controversial'' or ''inflammatory.'' *CTIA,* 928 F.3d at 847 (holding that sentence of mandated disclosure about cell-phone radiation that ''tells consumers what to do in order to avoid exceeding federal guidelines'' ''may not be reassuring, but it is hardly inflammatory. It provides in summary form information that the FCC has concluded that consumers should know in order to ensure their safety.''). There is no controversy about whether cigarette smoking causes the negative health consequences that form the content of the warnings. As discussed more fully in sections VI and VII, the evidence is clear that it does.

FDA also disagrees with comments that the warnings constitute a ''mini-billboard'' conveying an anti-smoking position on the part of the Government. FDA expresses no such viewpoint through these required health and safety disclosures: there is no ''provocatively-named'' ''1–800–QUIT–NOW'' hotline, and no man wearing a T-shirt emblazoned with ''I QUIT.'' Even though not implicated by the final warnings here, FDA disagrees with the suggestion that mandatory cessation messages, such as the current Surgeon General's warning dating to 1984, ''SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health, Birth, And Low Birth Weight,'' are ineligible for First Amendment review under *Zauderer.* Cessation statements, like the Surgeon General's warning just quoted, that contain factual and uncontroversial information are appropriately reviewed under the *Zauderer* standard just like other factual disclosures.

FDA also disagrees that its research studies confirm the warnings are not factual. Rather, through the Agency's science-based, iterative research process, FDA designed warnings that are factually accurate, have concordant textual statements and accompanying images depicting the specific health conditions, and are presented in a realistic and objective format. All warnings (new cigarette health warnings and the current Surgeon General's warnings, which served as the control condition) were perceived as being factual by the vast majority of participants in the consumer research studies. Importantly, we note that

''perceived factualness'' is distinct and different from actual factual accuracy. For example, when individuals are presented with new information, this new information may be viewed with skepticism and perceived as less factual than information that is familiar or well-known. We describe this in detail in section VI. FDA also disagrees with comments suggesting that the images are not factual because they are exaggerated, not typical, and therefore misleading (see section VII for further discussion). FDA disagrees with comments suggesting that its warnings are misleading because they should and do not take into account consumer understanding of either the relative risk of developing certain health conditions from smoking or the absolute risk of developing such conditions (see section VII.A).

c. Unduly Burdensome

(Comment 7) FDA received several comments stating that the required warnings violate the First Amendment because the size and placement requirements unduly burden speech and are broader than reasonably necessary. The comments raise concerns that each package must bear a required warning that will take up the top 50 percent of the package's front and rear panels and that cigarette advertisements must bear required warnings that occupy at least the top 20 percent of the advertisement. The comments note that communications with consumers are already limited due to bans on television and radio advertisements, promotional items, sponsoring events, and free samples. As alternatives, some comments suggest text-only warnings or public education campaigns.

Other comments say that the required warnings proposed by FDA do not unduly burden protected speech, noting that the size of the warnings on the packages and in advertisements is mandated by the Tobacco Control Act. One comment states there is no evidence that pictorial cigarette warnings covering 50 percent or more of the package have prevented companies from communicating their brand imagery in any of the over 100 countries that have implemented large health warnings. This comment notes that the health warnings provide additional information and do not prevent companies from communicating their promotional information.

(Response 7) FDA does not believe the warnings unduly burden protected speech. As the Sixth Circuit held, the Tobacco Control Act's warning requirement for cigarettes is not unduly burdensome because a manufacturer has ample opportunity to convey other information of its choosing in the remainder of the packaging or advertisement. *Discount Tobacco,* 674 F.3d at 530–31. By statute, the required warnings for cigarette packages must comprise the top 50 percent of the front and rear panels, and for advertisements at least 20 percent of the area at the top of the advertisement. The Sixth Circuit found that ''ample evidence support[s] the size requirements for the new warnings'' and ''that the remaining portions of their packaging'' are sufficient for the companies ''to place their brand names, logos or other information.'' *Id.* at 531, 567. See also *Spirit Airlines,* 687 F.3d at 414 (requirement for airlines to make total price the most prominent cost figure does not significantly burden airlines' ability to advertise). FDA also notes that, when the final rule is in effect, the area of cigarette package and advertising space currently devoted to the Surgeon General's warnings will be available for companies.

The Supreme Court's decision in *NIFLA* is not to the contrary. In *NIFLA,* the Court affirmed that, under *Zauderer,* required disclosures must ''extend no broader than reasonably necessary.'' 138 S. Ct. at 2377. This does not mean that a particular disclosure must be the least restrictive means of accomplishing the Government's objective. Here, FDA has concluded that the scientific literature strongly supports that larger warnings, such as those of the size required by Congress in the Tobacco Control Act and now being issued by FDA in this rule, are necessary to ensure that consumers notice, attend to, and read the messages conveyed by the warnings, which promotes improved understanding of the specific health consequences that are the subject of those warnings (Refs. 4 and 15). Furthermore, the exact size of the required warnings is not a constitutional issue. In *Burson* v. *Freeman,* 504 U.S. 191, 208 (1992), the Supreme Court, having determined that some restricted solicitation-free zone around a voting area was necessary to secure the State's compelling interest in fair elections, considered whether a 100-foot restricted zone was permissible or sufficiently tailored. The Court found that, although there were outside limits on how large the restricted zone could be, the difference between 25 and 100 feet was not ''of a constitutional dimension.'' *Id.* at 210–11. Because FDA has shown that the larger warnings at issue are reasonably necessary to achieve the Government's interest in promoting greater public understanding of the risks of smoking, and because manufacturers retain adequate space in which to undertake their preferred speech, the warnings are not unduly burdensome.

(Comment 8) Some comments state that the requirement to place warnings on the top 50 percent of front and rear panels means that all cigarette packages will look alike when placed in display cases which show only the top halves of cigarette packages, and the requirement will thus inhibit manufacturers' abilities to promote their branded products.

(Response 8) As noted elsewhere, and in accordance with the Sixth Circuit decision in *Discount Tobacco,* 674 F.3d at 530–31, 567, FDA has determined that the statutorily-required placement of warnings at the top 50 percent of front and rear panels of cigarette packages, and the top 20 percent of advertisements, leaves sufficient room for manufacturer speech. There is ample room for manufacturers to distinguish their products from other products using the lower half of a cigarette package and the remaining 80 percent of advertisements for brand names, logos, or other information. There is also additional space on the side panels of cigarette packages due to the removal of the Surgeon General's warnings. Although one comment expresses concern that the rule will render cigarette packages indistinguishable from one another because of certain display cases that show only the top portions of cigarette packages, there is no requirement that display cases be configured that way. Moreover, FDA observes that cigarette display fixtures and cases generally do not display only cigarette package facings, but commonly feature a large amount of ''header,'' ''flipper,'' and other cigarette advertising that is subject only to a 20 percent requirement. The requirements here are distinct from the disclosure requirements found unconstitutional in *NIFLA,* which mandated that the required statement be provided in up to 13 languages, thereby threating to ''drown out'' the speaker's own message. 138 S. Ct. at 2378. Here, any such concern is obviated because manufacturers retain 50 percent of the front and rear panels of cigarette packages, and 80 percent of advertisements, for their speech.

(Comment 9) One comment on the RIA suggested that the cigarette companies' reduced ability to communicate branding and other messages through their packs may result in lost communication potential.

(Response 9) We also address the same comment in the Final RIA (Ref. 16). The Final RIA includes an estimate of the immediate costs of a requirement

for warnings to use 20 percent of advertising space. But acknowledging that some economic costs may be associated with a mandatory disclosure provides very little information for any First Amendment analysis. The pertinent constitutional question is instead whether the mandatory disclosure is unduly burdensome and chills protected commercial speech, or whether manufacturers retain adequate space for their speech. *See Zauderer,* 471 U.S. at 651; *see also id.* at 653 n.15 (finding that ''[t]his case does not provide any factual basis for finding Ohio's disclosure requirements are unduly burdensome''); *cf. id.* at 663 (Brennan, J., joined by Marshall, J., concurring in part, concurring in the judgment in part, and dissenting in part) (concluding that the majority implicitly acknowledged that a mandatory disclosure, pages long, of ''detailed fee information that would fill far more space than the advertisement itself, would chill the publication of protected commercial speech''). As discussed elsewhere in this rule, FDA concludes that the remaining 80 percent of advertisements, and the remaining 50 percent of the principal panel of cigarette packages, provide adequate space for manufacturers' branding and messaging.

3. Central Hudson and Strict Scrutiny

(Comment 10) FDA received other comments suggesting that the required warnings are impermissible speaker-, content-, and viewpoint-based regulations of speech. These comments assert that the required warnings FDA proposed would fail under intermediate (*Central Hudson*) scrutiny because FDA has not shown that the warnings would materially and directly advance the substantial Government interest of promoting greater public understanding of the negative health consequences of smoking. The comments suggest that the problem the Government seeks to address is not real because smokers are already aware of the risks of cigarette smoking. Some comments add that even if the focus is on less-known risks, FDA has not shown that promoting greater public understanding of these risks is a substantial interest. Comments further assert that there would be more narrowly tailored means of addressing those less-known risks, for example, through public health campaigns. Conversely, other comments state that the proposed rule would be constitutional under intermediate scrutiny because FDA has a substantial interest in ensuring that consumers have accurate, factual information about the serious health effects of using products that are offered to them and these required warnings would directly advance that interest, as shown by FDA's quantitative consumer research (Refs. 12 and 17). Finally, at least one comment suggests the warnings are subject to strict scrutiny and cannot survive that standard.

(Response 10) FDA has determined that the warnings also would be constitutional if reviewed under intermediate scrutiny. Under the test for restrictions on commercial speech articulated in *Central Hudson Gas & Elec. Corp.* v. *Pub. Serv. Comm'n,* 447 U.S. 557 (1980), agencies can regulate commercial speech where the regulation directly advances a substantial Government interest and is not more extensive than necessary to serve that interest. *Central Hudson* does not require that the means chosen by the Government be the least restrictive means available for addressing an issue, see *Boards of Trustees.* v. *Fox,* 492 U.S. 469, 480 (1989), but the Supreme Court has in any event observed that required factual disclosures are less intrusive from a First Amendment perspective than are restrictions on speech. *Zauderer,* 471 U.S. at 651. Because the Government's interest in these warnings is substantial and the regulation is no more extensive than necessary to directly advance that interest, the rule withstands review even under *Central Hudson.*

As outlined in the preceding paragraphs of this section of the preamble, the risks associated with cigarette smoking present a significant public health problem, and the Government's interest in promoting greater public understanding of those risks is substantial. The scientific evidence produced by FDA's quantitative consumer research demonstrates that the required warnings in this rule directly advance the Government's interest by outperforming the current Surgeon General's warnings in actually providing ''new information'' and ''self-reported learning,'' which promote better understanding by the public about the negative health consequences of smoking, among other measured outcomes. As discussed elsewhere, the warnings are no more extensive than necessary to achieve the Government's interest—they provide factual and accurate representations of the dangers of cigarette smoking and apply to all cigarette packages and advertisements by all manufacturers, distributors, and retailers, so they are not over- or underinclusive in scope, and there is enough room remaining on the rest of the packages and advertisements for manufacturers to convey their messages.

Although some comments assert correctly that public health campaigns can be effective in helping raise general awareness of the health risks of using tobacco products, such campaigns may supplement but are not an adequate alternative to placing warnings directly on cigarette packages and advertisements for purposes of advancing the Government's interest. Congress has long required that cigarette warnings appear on packages and in advertisements. As far back as 1965, the FCLAA set forth the policy of a comprehensive warning program on cigarette packages and advertisements so that ''the public may be adequately informed'' about the dangers of cigarette smoking. FCLAA Section 2(1), codified at 15 U.S.C. 1331(1). This reflects the recognition that, while voluntary public education campaigns can provide effective targeting and messaging, they do not reach every person who looks at a package of cigarettes or advertisements and do not receive as many impressions as a comprehensive program of cigarette package and cigarette advertisement warnings. Studies demonstrate that pictorial cigarette warnings placed directly on products convey the risks to those who look at packages and advertisements with more immediacy and noticeability (see section VI.B for further discussion). Therefore, FDA disagrees that public education campaigns are adequate alternatives for warnings on packages and advertisements.

Regarding the proposed alternative of text-only warnings, the scientific literature strongly supports that pictorial cigarette warnings promote greater public understanding about the health consequences of smoking as, for example, they: (1) Increase the noticeability of the warning's messages; (2) increase knowledge and learning of the negative health consequences of smoking; and (3) benefit subpopulations that have disparities in knowledge about the negative health consequences of smoking (see section V.B of the proposed rule, 84 FR at 42762–65). When Congress amended the FCLAA with the Tobacco Control Act, it recognized that the current 1984 Surgeon General's text-only warnings had become ''ineffective in providing adequate warnings about the dangers of tobacco products'' (Ref. 14 at 4). To that end, Congress directed new cigarette warnings to be accompanied by color graphics. FDA's quantitative consumer research studies show that the new required warnings with color graphics promote greater understanding of the

negative health consequences of smoking than the current 1984 Surgeon General's warnings, which served as the control condition. Each of the final required warnings outperformed the Surgeon General's warnings on the two outcomes FDA specified (as described in section VI.E of the proposed rule, 84 FR at 42771–72) as being predictive for promoting understanding of the risks associated with cigarette smoking: ''new information'' and ''self-reported learning.'' In addition, the final required warnings also demonstrated statistically significant greater scores in nearly all other measures of understanding when compared to the Surgeon General's warnings (see section VII.B below for a discussion of the study results for each required warning). There is ample scientific evidence that textual warnings accompanied by large color images will directly advance greater public understanding of the negative health consequences of smoking.

We disagree with the comment that suggests that the required warnings are compelled speech that would be subject to strict scrutiny as content-based regulation of commercial speech, citing *Reed* v. *Town of Gilbert,* 135 S.Ct. 2218, 2226 (2015), *Sorrell* v. *IMS Health Inc.,* 564 U.S. 552 (2011), and *NIFLA.* The rule is properly reviewed under *Zauderer* but would also easily survive scrutiny under *Central Hudson.*

In *Reed* v. *Town of Gilbert,* the Court applied strict scrutiny to content-based restrictions on non-commercial speech in public fora. *Reed* had nothing to do with commercial speech doctrines, much less with the type of disclosure required by this final rule, and it has not been understood to alter the applicability of *Central Hudson* or *Zauderer.* Likewise, *Sorrell* ''did not mark a fundamental departure from *Central Hudson's* four-factor test, and *Central Hudson* continues to apply'' to regulations of commercial speech, regardless of whether they are content based. *Retail Digital Network, LLC* v. *Prieto,* 861 F.3d 839, 846 (9th Cir. 2017) (en banc); accord *Missouri Broad. Ass'n* v. *Lacy,* 846 F.3d 295, 300 n.5 (8th Cir. 2017). The Supreme Court has never applied strict scrutiny to regulations of this type, notwithstanding that they generally apply only to a specific type of commercial activity, and may thus concern a particular subject. To the contrary, in *NIFLA,* which post-dates both *Reed* and *Sorrell,* the Court reaffirmed that it did ''not question the legality of health and safety warnings long considered permissible, or purely factual and uncontroversial disclosures about commercial products.'' *NIFLA,* 138 S. Ct. at 2376.

4. Constitutionality of Statutory Requirement

(Comment 11) Several comments argue that the statutory requirement for ''graphic'' health warning labels in the Tobacco Control Act itself violates the First Amendment. Other comments express strong support for the cigarette health warning label requirement in the Tobacco Control Act, noting that this provision of the Tobacco Control Act was upheld in *Discount Tobacco,* 674 F.3d 509 (6th Cir. 2012).

(Response 11) Comments addressed to the facial constitutionality of a statute are generally outside the scope of an agency's rulemaking authority. *Am. Meat Inst.,* 760 F.3d at 25 (''We do not think the constitutionality of a statute should bobble up and down at an administration's discretion.''). The statutory requirement for cigarette health warning labels was in any event considered in a facial challenge and upheld by the Sixth Circuit in *Discount Tobacco City,* and the Supreme Court denied the manufacturers' petition for a writ of certiorari (569 U.S. 946 (2013)). For the reasons stated in that opinion, and for the additional reasons stated in the preceding paragraphs of this section of the preamble explaining why the final rule is constitutional, the statutory ''graphic label statement'' requirement is consistent with the First Amendment.

D. Comments Regarding the Administrative Procedure Act (APA)

FDA received comments on a range of APA issues, including general objections that the rule is not the result of deliberative and reasoned decision making and comments that assert FDA failed to support the Agency's findings, ignored alternative evidence, and failed to provide an opportunity to meaningfully comment. Several comments generally note that under the APA courts will set aside a rule if the rule exceeds the Agency's authority, fails to comply with statutory requirements or consider alternatives, or if the action is otherwise arbitrary, capricious, or an abuse of discretion. As discussed in detail in the following paragraphs, FDA has carefully considered and responded to the APA issues raised in the comments.

1. Adequacy of the Evidence in Support of the Rule

(Comment 12) Several comments assert that the proposed rule violated the APA because under the APA, FDA must engage in ''reasoned decision-making'' and FDA violated the APA by failing to develop affirmative ''substantial evidence'' to support the rule or, alternatively, because FDA relied on evidence that does not support the rule. Some comments suggest that FDA violated the APA by not developing a record to support the rule but instead issued the rule based on ''speculation, conjecture, or supposition'' and that FDA based the proposed rule either on: ''(1) a hypothetical reduction in smoking not supported by the record, or (2) a hypothetical problem, lack of consumer awareness of the harms of smoking.''

More specifically, some comments argue that FDA has failed under the APA to articulate a rational explanation for the required warnings included in the proposed rule. Comments said that if FDA's interest is consumer awareness, then consumers do not need to be informed of the risks of smoking because there is ample evidence that consumers are well aware of the health risks of cigarette smoking. Other comments argue that FDA's research is flawed as it is inherently biased and fails to account for potential confounding variables and did not reliably test ''whether study participants actually learn anything new.'' With respect to FDA's final quantitative consumer research study, some comments suggest FDA also failed to test whether the proposed images add any new information above and beyond the new text and failed to control for the effect of altering the warnings' size and location. Another comment objects to the final quantitative study as flawed because FDA failed to incorporate the commenter's suggestions on demographic and other factors. Some comments state that both quantitative studies are also flawed as they did not test comprehension or understanding of the revised textual statements or images and because they enrolled non-representative participants. These comments also argue that FDA's quantitative studies fail to support the proposed required warnings because the study results demonstrate low or no impact of several tested statements or statement-and-image pairings. Other comments suggest that FDA inappropriately relied on non-U.S. studies and on other studies that have design or execution limitations, including lack of comparative effectiveness data, no measurement of understanding, and no evaluation of whether the image contributes to understanding over and above text.

Other comments suggest that if the rule is based on an interest in a reduction in smoking, then FDA has provided no evidence, including no consumer perception and actual use data, that the proposed required

warnings would decrease smoking initiation and increase smoking cessation.

(Response 12) FDA disagrees with comments suggesting that the rationale for and evidentiary basis supporting this rule are inadequate. Rather, FDA has both documented the need for this rule and developed a robust record supporting it. As the record demonstrates, the final cigarette health warnings will promote greater public understanding of the negative health consequences of smoking.

The rationale for the rule is clear. Cigarette smoking remains the leading cause of preventable disease and death in the United States, yet the public continues to hold misperceptions about the health risks of smoking and is largely unaware of certain conditions caused by smoking (see section V for further discussion). We disagree with comments that argue the public's knowledge of the general harms of cigarette smoking undercuts the need for these required warnings. Contrary to some comments' discussion of the PATH data, there remain large gaps in knowledge about the health effects of smoking, with many smokers having little awareness of the wide variety of diseases causally linked to smoking (see section V.B for further discussion). As discussed in more detail in the First Amendment section, the Sixth Circuit concluded that ''[t]here can be no doubt that the government has a significant interest in . . . warning the general public about the harms associated with the use of tobacco products.'' *Discount Tobacco,* 674 F.3d 509, 519 (6th Cir. 2012).

FDA also disagrees that the Agency's research fails to support this rule or that different warning elements should have been tested. FDA undertook a rigorous science-based, iterative research process to develop and test cigarette health warnings depicting the negative health consequences of smoking. FDA's process involved carefully reviewing the scientific literature on the health risks associated with cigarette smoking, evaluating the public's general awareness and knowledge of those health risks, and assessing the Agency's own consumer research on potential revised warning statements (see section VI for further discussion). The Agency's findings as a result of this process showed that the selected pairings of text and pictorial warnings would promote greater public understanding of the negative health consequences of cigarette smoking. FDA further disagrees with comments suggesting that FDA's reliance on other studies in developing its warnings is inappropriate (see section V.B.2 for further discussion).

Accordingly, the proposed rule is justified by the Government's interest in promoting greater public understanding of the negative health consequences of smoking. To the extent some comments suggest that FDA did not prove that the warnings will lead to increased smoking cessation or decreased initiation, FDA notes that increased smoking cessation and decreased initiation are not the purpose of this rule.

(Comment 13) One comment states there is no evidence to support FDA's proposal to include two different images with the textual warning statement of ''WARNING: Smoking causes COPD, a lung disease that can be fatal.''

(Response 13) FDA is finalizing only one text-and-image pairing for the textual warning statement, ''WARNING: Smoking causes COPD, a lung disease that can be fatal.''

2. Consideration of Contrary Scientific Evidence

(Comment 14) Some comments suggest that FDA did not adequately consider contrary scientific evidence that undermines the proposed rule, including evidence showing that graphic warnings are ineffective in improving consumer comprehension; evidence showing ''shocking images'' to be less effective; evidence showing that gruesome images can be seen as exaggerating risks and thus ignored; evidence showing that ''fear-based'' messages can be ignored or perceived in a defensive manner; or evidence showing that consumers already understand the health consequences of smoking. Comments assert that FDA did not address evidence indicating that the statutory size requirements for warnings on packages and advertisements do not advance consumer understanding.

(Response 14) FDA disagrees with comments suggesting FDA did not adequately consider contrary scientific evidence. As discussed in greater detail below, FDA concludes that those studies with findings contrary to FDA's conclusion regarding images promoting greater understanding may be partly or fully attributable to the fact that the public already has a high pre-existing level of knowledge of the specific health consequences described in the warnings tested in those studies (see section V.B.2 for further discussion). With respect to the evidence about the size of the warnings, the proposed required warnings were tested in the sizes specified by section 4 of the FCLAA. The data generated from FDA's final quantitative consumer research study demonstrate that the 11 final required warnings increase understanding of the negative health consequences of cigarette smoking.

3. Consideration of Alternatives

(Comment 15) Comments state that FDA did not adequately evaluate alternatives to the proposed rule, such as refreshing the Surgeon General's warnings or requiring new, text-only warnings. Other comments suggest that FDA should evaluate the alternatives of smaller or differently placed warnings, or the use of ''enhanced public education campaigns.''

(Response 15) FDA disagrees with comments suggesting that its consideration of alternatives was inadequate. FDA considered many approaches, including text-only warnings or different graphic approaches, throughout its process. Ultimately, FDA was guided both by Congress's directive to issue regulations with color graphics to accompany new textual warnings and, as described more fully in section VI of the proposed rule, by findings from health communication science research regarding best practices for communicating health risk information to the lay public.

In amending the FCLAA with the Tobacco Control Act, Congress explicitly recognized that the Surgeon General's text-only warnings had become ''ineffective in providing adequate warnings about the dangers of tobacco products'' (Ref. 14 at 4). To that end, Congress mandated new cigarette textual warning statements to be accompanied by color graphics. Given this directive, testing text-only warnings would not have been an optimal use of FDA's resources. FDA did, however, consider the substantial body of scientific evidence showing that cigarette textual warning statements better promote public understanding of health risks when accompanied by color graphics. Furthermore, as discussed in section VI, FDA's research studies show that the new warnings with accompanying color graphics promote greater understanding of the risks of smoking than the controls consisting of the (text-only) Surgeon General's warnings (see, also, section V of the proposed rule for a discussion of the literature on the benefits of large pictorial cigarette health warnings).

With regard to comments suggesting that FDA should have considered smaller or differently placed warnings, FDA disagrees. The statute sets forth the requirements with regard to size and placement of the warnings, and the scientific literature strongly supports that larger warnings, such as those of the size proposed in this rule, are

necessary to ensure that consumers notice, attend to, and read the messages conveyed by the warnings, which leads to improved understanding of the specific health consequences that are the subject of those warnings (Refs. 4 and 15). The placement of the warnings at the top 50 percent of the front and rear panels of the packages and at least the top 20 percent of advertisements will better ensure noticeability of the warnings. Moreover, the Supreme Court has recognized that decisions with respect to the constitutionality of a regulation do not include second-guessing the details of such regulations. In *Burson* v. *Freeman,* 504 U.S. at 210–11, the Court, having determined that some restricted zone around a voting area was necessary to secure the State's compelling interest, recognized that the exact size of that space was not a constitutional question. Rather, the constitutional question lies in the outer bounds of a regulation; various permutations within those bounds is a matter for legislators.

FDA also disagrees with comments that FDA should have pursued enhanced public education efforts rather than issuing new warnings. As discussed more fully in the First Amendment section, while public health campaigns can allow for effective targeting and messaging, they do not reach every person who looks at a package of cigarettes or advertisements and do not receive as many impressions as a comprehensive program of cigarette package and cigarette advertisement warnings. Studies demonstrate that pictorial cigarette warnings placed directly on products convey the risks with more immediacy and noticeability (see section VI.B for further discussion). Accordingly, new warnings with color graphics for packages and advertisements will promote greater public understanding of the risks of smoking.

4. Meaningful Opportunity To Comment

(Comment 16) FDA received comments asserting that the Agency failed to provide an opportunity to meaningfully comment under the APA because FDA did not fully disclose the data, methodologies, summaries, and conclusions relied on to support the proposed rule. Some comments argue that 60 days is not enough time to comment given the complexity of the proposed rule and does not provide the public sufficient time to develop alternative warnings, and one comment requests an extension of the comment period. The comments note that FDA spent years developing the proposed rule and emphasized throughout the proposed rule the complex process the Agency undertook to develop the required warnings. Some comments suggest FDA made errors due to a court order which, they contend, forced the Agency to rush through the final stages of rulemaking or that FDA did not provide sufficient time because the Agency does not intend to consider alternatives. One comment requests a response to a Freedom of Information Act request as essential to being able to meaningfully respond to comments.

(Response 16) We disagree with these comments. Although the Agency is under a court order to send the final rule to the Office of the Federal Register by a specific date, FDA provided a standard 60-day comment period for the proposed rule and the Agency has thoroughly reviewed and responded to all public comments and made changes that are reflected in the final rule based on public input. While the Agency supplemented the docket with requested background information (84 FR 60966, November 12, 2019), as discussed below these qualitative studies are not key data relied upon by the Agency to make final decisions about the proposed and final rules.

As explained in section VI of the proposed rule, FDA conducted various qualitative focus groups and interviews (''qualitative studies'') to test and refine image concepts for the required warnings and to obtain feedback on which textual statements should be selected for further study. In general, qualitative research is used to understand how a research topic is experienced from the perspective of the study participants. It is typically conducted via indepth interviews, participant observation, or focus groups to obtain information about the attitudes, opinions, and behavior of particular populations. FDA did not include the qualitative study reports in the docket as the rulemaking itself did not directly rely upon them. However, because the qualitative studies did inform further FDA research and development, namely, the quantitative consumer research studies, FDA subsequently added these materials to the docket and reopened the comment period for 15 days to allow public input on the supplemental materials (84 FR 60966).

The APA does not include a specific procedural requirement for the length of time an agency must allow for comments. *See Phillips Petroleum Co.* v. *EPA,* 803 F.2d 545, 559 (10th Cir. 1986) (stating ''[t]his opportunity to participate is all that the APA requires''). FDA's regulations generally require that the Agency provide 60 days for comment on proposed regulations (21 CFR 10.40(b)(2)). The Commissioner may shorten or lengthen that time period for ''good cause,'' but in no event is the time for comment to be less than 10 days. *Id.* While FDA regulations permit an extension of comment periods, § 10.40(b)(3)(i), a request to do so ''must discuss the reason comments could not feasibly be submitted within the time permitted, or that important new information will shortly be available, or that sound public policy otherwise supports an extension of the time for comment.'' *Id.* When agencies have been challenged on abbreviated comment periods, courts generally look to whether shorter time frames were necessitated by deadlines for Agency action. *See, e.g., Omnipoint Corp.* v. *FCC,* 78 F.3d 620, 629–630 (D.C. Cir. 1996) (rejecting a challenge to a 15–day comment period given a ''congressional mandate [to act] without administrative or judicial delays'') (internal quotations and citation omitted); *Fla. Power & Light Co.* v. *United States,* 846 F.2d 765, 772 (D.C. Cir. 1987) (determining that a 15-day comment period did not violate the APA where the Nuclear Regulatory Commission was under a Congressionally imposed deadline). Courts considering whether a public comment period was long enough also look in particular to whether there is evidence that interested parties did in fact submit meaningful comments. *See, e.g., Fla. Power & Light,* 846 F.2d at 772 (finding ''no evidence that petitioners were harmed by the short comment period,'' where the Commission ''received sixty-one comments, some of them lengthy, addressing its proposed rule'' and ''[t]hose comments had a measurable effect on the final rule'') *Conference of State Bank Sup'rs* v. *Office of Thrift Supervision,* 792 F. Supp. 837, 844 (D.D.C. 1992) (rejecting argument that 30-day comment period was inadequate, ''especially in light of the comments that [aggrieved plaintiffs] and other interested parties submitted in response to this proposed rule'') (citing 12 pages of comments in administrative record).

Here, the Agency received numerous meaningful comments both in support of and disagreeing with the proposed rule, totaling thousands of pages. The Agency has not only taken those public comments into consideration in issuing this final rule, but also made changes to the final requirements based on that public feedback, including allowing cigarette manufacturers to use different required warnings on the front and rear panels of a cigarette package, and altering the image of the underweight

baby on a scale to improve image clarity. The initial 60-day period and supplemental 15-day period for public comment on the notice of proposed rulemaking provided ample opportunity for public participation in this rulemaking process, and comments have failed to establish a basis under § 10.40(b)(3)(i) for any further extensions of time.

5. Requirement of Random and Equal Distribution

(Comment 17) Comments assert that the random and equal distribution requirement for cigarette packages as applied to the proposed 13 warnings is arbitrary and capricious under the APA because compliance is impossible from a printing perspective. Comments urge that FDA must reduce the number of warnings and provide greater flexibility. These comments suggest FDA misunderstands the printing processes in the United States and that industry cannot comply, particularly in the time allotted. The comments explain the printing process and describe why requiring the random and equal distribution of thirteen warnings is ''infeasible.''

(Response 17) FDA is finalizing a set of 11 required warnings. FDA disagrees that the statute's and the final rule's requirement for random and equal display and distribution of cigarette package warnings violates the APA. A standardized number of warnings—11 in this final rule, reduced from 13 in the proposed rule—gives the industry a known quantity to implement, and the statute and final rule provides for a 15-month period in which to adjust any printing processes that may require updating. In addition, as we discuss in our responses to the comments that describe implementation concerns (see section X), in preparation for submission of a cigarette plan, FDA encourages manufacturers to engage with FDA sooner rather than later on specific issues related to their product (see also section IX.B.4.e).

V. Need for Rule and FDA Responses to Comments

A. Cigarette Use in the United States and the Resulting Health Consequences

1. Smoking Prevalence and Initiation in the United States

In explaining the need for the proposed rule, we provided information on smoking prevalence and initiation rates among adults and children in the United States. As stated in the proposed rule, cigarettes remain the most commonly used tobacco product in the United States among adults, and a substantial percentage of U.S. adults are cigarette smokers (Ref. 18). Although cigarette smoking prevalence has generally declined over the past several decades, approximately 34.2 million U.S. adults smoke cigarettes, and, among these adult smokers, the vast majority—74.6 percent, or approximately 25.5 million people—smoke every day. Smoking prevalence remains higher than the national average among certain demographic subgroups of the adult population. For example, among adults with differing levels of education, the highest prevalence rates have been observed in adults with lower education levels. Data indicate that 36.0 percent of adults with a General Education Development certificate and 21.8 percent of adults with less than a high school diploma were current smokers in 2018, compared with 7.1 percent of adults with a college degree and 3.7 percent of adults with a graduate degree (Ref. 19).

Despite recent declines in youth smoking rates, the 2019 National Youth Tobacco Survey data showed that past 30-day smoking prevalence among high school students was 5.8 percent, representing 860,000 youth, of which 32.5 percent were frequent smokers (defined as cigarette use on 20 or more of the past 30 days) (Refs. 20 and 21). The data also showed that past 30-day prevalence among middle school students was 2.3 percent, representing 270,000 youth (Ref. 20). Results from the 2018 National Survey on Drug Use and Health demonstrate that, on average, each day in the United States, approximately 1,600 youth ages 12 to 17 smoke their first cigarette, and 170 youth ages 12 to 17 become daily cigarette smokers (Ref. 22 at Table A.3A).

2. Negative Health Consequences of Smoking

As described in the proposed rule, the health risks associated with cigarette smoking are significant. Cigarette smoking remains the leading cause of preventable disease and death in the United States and is responsible for more than 480,000 deaths per year among cigarette smokers and those exposed to secondhand smoke (Ref. 3). Smoking causes more deaths each year than human immunodeficiency virus, illegal drug use, alcohol use, motor vehicle injuries, and firearm-related incidents combined (Refs. 23 and 24). Over 16 million Americans alive today live with disease caused by smoking cigarettes (Ref. 3).

Since the first Surgeon General's Report published in 1964, evidence of the negative health consequences of cigarette smoking and secondhand smoke has expanded dramatically. For example, the 2014 Surgeon General's Report (Ref. 3) presented a robust body of scientific evidence documenting the health consequences from both smoking and exposure to secondhand smoke across a range of diseases and organ systems. In particular, the 2014 Surgeon General's Report added eleven diseases to the long list of diseases causally linked to cigarette smoking: Liver cancer, colorectal cancer, age-related macular degeneration, orofacial clefts in newborns from maternal smoking during pregnancy, tuberculosis, stroke (for adults), diabetes, erectile dysfunction, ectopic pregnancy, rheumatoid arthritis, and impaired immune function (Ref. 3 at pp. 4–5). The health conditions established to be causally linked to cigarette smoking in the 2014 Surgeon General's Report are in addition to the more than 40 unique health consequences of cigarette smoking and exposure to secondhand smoke determined by earlier studies (Ref. 3).

FDA received many comments that were strongly supportive of the proposed rule, many of which reiterate the negative health consequences of cigarette smoking described in the proposed rule and stressed the need for public health measures, such as new cigarette health warnings, to communicate the latest science to the public. FDA did not receive comments disputing that cigarette smoking is harmful to human health.

(Comment 18) Several comments emphasize that, given the substantial health toll of tobacco use, ''it is difficult to imagine a more compelling governmental interest than to ensure that the public understands the health consequences of smoking'' and that health warnings on cigarettes are one of the most efficient and effective ways of doing so.

(Response 18) FDA agrees that the health toll from cigarettes is substantial and that the required warnings in the final rule will improve public understanding about the breadth of negative health consequences caused by smoking. As explained in section V.B of the proposed rule, the scientific literature demonstrates that cigarette health warnings that are noticeable, lead to learning, and increase knowledge will promote greater public understanding of the negative health consequences of smoking, and FDA's consumer research has demonstrated that the required warnings will advance this important governmental interest.

(Comment 19) A comment (from a public health group and a network of

state and territorial tobacco prevention and control programs across the United States) expressed support for FDA to fully implement all of the warnings in the proposed rule. The comment states the rule is complementary to the needs and goals of public health agencies and that the required warnings on cigarette packs and advertisements will effectively and appropriately support state and territory-based efforts to educate smoking and nonsmoking consumers.

(Response 19) FDA agrees that the final rule will complement other educational efforts that inform smokers and nonsmokers about the negative health consequences of smoking. As we discuss in section VII, following consideration of the public comments received in the docket, as well as based on the results of our consumer research studies, existing scientific literature on cigarette health warnings, and legal and policy considerations, FDA is finalizing 11 of the 13 required warnings.

(Comment 20) Some comments provide additional information that smoking disproportionately harms (through both higher prevalence and tobacco-related death and disease) many marginalized populations, including African-Americans; American Indians, and Alaskan Natives; people with low incomes, low educational attainment, and low health literacy; people who identify as lesbian, gay, bisexual, or transgender; and people with behavioral health and substance use conditions (see, *e.g.,* Refs. 25–28).

(Response 20) FDA agrees that cigarette smoking disparities exist among specific subpopulations in the United States. As described in section IV.A of the proposed rule, smoking prevalence is higher in some subpopulations (*e.g.,* those with lower socioeconomic status (SES)) than the general U.S. population (Refs. 18, 29, and 30). For the reasons explained in section V.B.2 of the proposed rule, some subpopulations experience disparities in knowledge of the health harms of smoking due to lower health information access and lower health literacy, and the evidence collectively demonstrates that pictorial cigarette warnings, such as the required warnings being issued in this final rule, are effective across diverse populations and settings and will likely help reduce disparities found in consumer understanding about the harms of smoking.

B. Data Concerning Cigarette Health Warnings

1. The Current 1984 Surgeon General's Warnings Are Inadequate

In the preamble to the proposed rule, FDA observed that cigarette packages and advertisements can serve as important channels for communicating health information to broad audiences that include both smokers and nonsmokers. Daily smokers are potentially exposed to the warnings on packages over 5,100 times per year, and, because these packages are not always concealed and are often visible to those other than the person carrying the package, including retail customers, warnings on those packages are potentially viewed by many others, including nonsmokers (Refs. 31 and 32). Smokers and nonsmokers, including adolescents, also are frequently exposed to cigarette advertising appearing in a range of marketing channels, including print and digital media, outdoor locations, and in and around retail establishments where tobacco products are sold (Refs. 33 and 34). The inclusion of health warnings on cigarette packages and in advertisements therefore can provide a critical opportunity to help smokers and nonsmokers of all ages better understand the negative health consequences of smoking. However, the current 1984 Surgeon General's warnings have suffered from three critical problems: (1) They have not changed in more than 35 years and long ago became effectively stale; (2) they do not effectively promote greater public understanding of the risks of smoking because they do not attract attention, are not remembered, and do not prompt thoughts about the risks of smoking; and (3) they do not address areas where there are significant gaps in public understanding about the negative health consequences of cigarette smoking (see section V.A of the proposed rule).

The proposed rule presented extensive evidence from the scientific literature regarding how the current 1984 Surgeon General's warnings are largely unnoticed and unconsidered by both smokers and nonsmokers (see section V.A.2 of the proposed rule). FDA also provided clear evidence that consumers suffer from a pervasive lack of knowledge about and understanding of many of the negative health consequences of smoking and the current Surgeon General's warnings are inadequate to address these knowledge gaps.

We received numerous comments supporting our analysis regarding the inadequacy of the current 1984 Surgeon General's warnings that appear on cigarette packages and in cigarette advertisements. FDA also received many comments regarding the level of consumers' knowledge and understanding of the health risks of smoking. Several comments stated that the public is adequately informed about the risks of smoking, while many other comments explained that consumers lack knowledge about a wide variety of smoking risks. These comments, and our responses, are summarized below.

(Comment 21) A substantial number of comments strongly support the proposed rule and urge FDA to include all 13 proposed required warnings in the final rule. These comments cite as support: The more than 35 years since the current 1984 Surgeon General's warning labels were changed; the conclusion that the current Surgeon General's warnings are ''wholly inadequate'' because they are not noticed and fail to address many of the health harms of smoking of which the public has little knowledge; the demonstrated gaps in public awareness and knowledge of the health risks of tobacco use; the well-established and ''overwhelming'' findings that large pictorial cigarette warnings such as those included in the proposed rule can effectively promote public awareness and understanding of the negative health consequences of smoking through conveying the risks of smoking and secondhand smoke (Ref. 35); and FDA's scientific evidence and research studies establishing that the proposed warnings will advance the Government's interest in promoting greater public understanding of the negative health consequences of cigarette smoking.

(Response 21) FDA agrees that there is a strong need for new cigarette health warnings because, as noted in section V.A of the proposed rule, the current 1984 Surgeon General's warnings are inadequate because they do not attract attention, are not noticed, do not prompt consumers to think about the risks of smoking, are not remembered, do not address the breadth of negative health consequences of smoking, and have not been updated in more than 35 years. FDA agrees that large pictorial cigarette warnings, such as the ones required in the final rule, will address the noted issues by attracting attention and focusing on less-known health consequences of smoking to promote greater public understanding of the negative health consequences of smoking (see section V.B of the proposed rule and section V.B of the final rule).

(Comment 22) Several comments strongly support FDA's aim in issuing

new cigarette health warnings, which is to promote greater public understanding of the negative health consequences of smoking. One comment from an academic researcher states that the proposed warnings' focus on ''novel'' health effects, for which there are lower levels of public awareness, is an appropriate and effective strategy. Comments from multiple professional medical associations emphasize that their medical professional members know first-hand the devastating impact of tobacco-related death and disease on the patients, including children, they treat in their clinical practice every day. Many comments from public health providers and advocacy groups, including those caring for children, strongly encourage FDA to finalize the proposed rule as quickly as possible (no later than the federal court deadline) and to implement the enhanced warning labels without further delay. Another comment, submitted by an academic researcher, emphasizes that the proposed rule presents a ''unique opportunity'' to educate consumers on some of the less-known health effects of tobacco use, including bladder cancer, erectile dysfunction, and diabetes, stating that ''these health effects are among those that consumers and the general public in the U.S. are largely less aware,'' according to research conducted by the researcher.

(Response 22) As described in the proposed rule, when developing the new cigarette health warnings, FDA consulted the epidemiological literature of causally-linked health conditions as identified in the Surgeon General's Reports and scientific literature (see sections VI.A and VII.A of the proposed rule). FDA developed cigarette health warnings that focus on negative health effects that are less known or less understood by consumers. FDA agrees that the required warnings, once implemented, will promote greater public understanding of the negative health consequences of smoking.

(Comment 23) A number of comments support FDA's finding that the current 1984 Surgeon General's warnings are inadequate and not taken seriously by consumers, public understanding of the health impacts of smoking is still limited, and large, pictorial cigarette warnings can increase knowledge of the health harms of smoking. Some comments discuss the wide range of studies that indicate that the existing warnings on cigarette packages and in cigarette advertisements are substantially less effective at communicating the health effects of smoking than larger pictorial cigarette warnings and are associated with substantial disparities in health knowledge.

(Response 23) FDA agrees with these supportive comments that the current 1984 Surgeon General's warnings on cigarette packages and in cigarette advertisements are inadequate and ineffective in communicating the health harms of smoking and that the larger pictorial warnings required by this rule will be more effective in helping promote greater public understanding of the negative health consequences of smoking.

(Comment 24) A comment asserts that FDA's proposed rule references some published studies that are older, do not specifically address the current state of the public's knowledge, or focus on smoking-related health effects (*e.g.,* cervical cancer, infertility, kidney cancer, osteoporosis) that are not found in the proposed warnings. The comment states that none of the studies are directly relevant in showing what the U.S. population currently knows about the health risks identified in the proposed required warnings.

(Response 24) To examine public understanding of the negative health consequences of smoking within the U.S. population, FDA conducted qualitative and quantitative consumer research studies that recruited youth, young adults, older adults, smokers, and nonsmokers in addition to our review of the existing scientific literature. Our findings reinforced what is known about public misperceptions of the health harms of smoking while also addressing gaps that the comment identifies with updated and relevant scientific support.

As discussed in section V.A.3 of the proposed rule, 84 FR at 42761–62, consumers suffer from a pervasive lack of knowledge about and understanding of the many negative health consequences of smoking, and importantly, the published literature indicates that consumers do not understand the wide *range* of illnesses caused by smoking. Due to these gaps in public understanding about the negative health consequences of smoking, as seen in the literature, FDA developed the required warnings to cover a range of smoking-related health effects (as described in section VI of the proposed rule) in order to improve public understanding (see section V.B.2 of the proposed rule, 84 FR at 42763–65 (''Pictorial Cigarette Warnings Can Address Gaps in Public Understanding About the Negative Health Consequences of Smoking'')). Additionally, FDA's rigorous science-based, iterative research and development process confirmed that there are substantial consumer knowledge gaps in in the United States and that the required warnings focusing on the specific health consequences highlighted will meet FDA's objectives, especially as indicated by outcomes of ''new information'' and ''self-reported learning'' (see section VI of the proposed rule and sections VI and VII of this final rule).

(Comment 25) Several comments discuss the disproportionate burden of smoking observed for some subgroups (*e.g.,* those with lower SES, non-English speakers) and state these subgroups also have disparities in knowledge about the negative harms of smoking. Several comments state that these subgroups tend to have lower levels of health literacy, limited access to information about the hazards of smoking, and tend to benefit the least from textual warnings on smoking harms. As a result, many comments state that cigarette health warnings with images depicting the harms of smoking will benefit these subgroups by effectively communicating the negative consequences of smoking to diverse populations.

(Response 25) FDA agrees. As discussed in section V.B.2.c of the proposed rule, 84 FR at 42764–65, research shows that pictorial cigarette warnings are effective for diverse populations that differ in cultural, racial, ethnic, and socioeconomic backgrounds. Pictorial cigarette warnings are likely to help reduce disparities among disadvantaged groups in consumer understanding about the harms of smoking.

(Comment 26) Two comments argue that individuals in the United States have substantial exposure to smoking-related information from a wide array of Federal, State, and other public health sources which results in high awareness of the negative health effects of smoking, rendering the proposed cigarette health warnings ineffective in increasing consumer understanding of the negative health consequences of smoking and that FDA has failed to address scientific evidence showing that consumers already understand the health consequences of smoking. In support of that argument, one comment describes survey findings from FDA's PATH, the Gallup Poll, and the National Survey on Drug Use and Health (NSDUH) that show high proportions of respondents indicating awareness that smoking cigarettes is generally harmful to one's health. Additionally, the comment submits an analysis of PATH data from adult respondents that describes perception measures of smoking-related health effects and associations with current smoking status. The comment also cites

published studies and draws the conclusions that the U.S. population has high levels of knowledge regarding general and specific smoking-related health effects, the public overestimates the risks of smoking, and the proposed cigarette health warnings would be ineffective at increasing consumer understanding of the negative consequences of smoking.

(Response 26) FDA disagrees with the view that the public already has a strong understanding of the health consequences of smoking. As discussed in section V.A.3. of the proposed rule, 84 FR at 42761–62, consumers suffer from a pervasive lack of knowledge about and understanding of many of the negative health consequences of smoking (see also section VI.A of the proposed rule, 84 FR at 42766–67, citing research studies finding that consumers are largely unaware of the negative health consequences of cigarette smoking not mentioned in current warnings, as well as more specific information about the negative health effects and their mechanisms). Moreover, and importantly, the published scientific literature indicates that consumers do not understand the wide range of illnesses caused by smoking. As discussed in section V.B.2 and VI.D of the proposed rule, 84 FR at 42763–64, 42770, pictorial cigarette warnings have been demonstrated to address these gaps in public understanding about the negative health consequences of smoking by conveying new information in a large and prominent format that will attract attention, be noticed, prompt consumers to think about the risks of smoking, and be remembered.

The data that the comment cites on general awareness of the harms of smoking in FDA's ongoing PATH study, the Gallup Poll, and NSDUH are not relevant to this rulemaking. The goal of the required warnings is not to increase perceptions of general harm of smoking as measured by questions in these surveys, such as ''How harmful do you think cigarettes are to health?'' or ''Do you think smoking is harmful to you?'' Rather, the goal is to promote greater public understanding of the negative health consequences of smoking as conveyed in the required warnings, which address specific health consequences rather than health consequences in the abstract.

The statement also describes an analysis of the publicly available PATH data from Wave 1 (2013–2014), Wave 2 (2014–2015), and Wave 3 (2015–2016). The comment's analysis attempts to examine perception measures of the specific health harms of smoking referenced in the required warnings. We have concerns with the analysis presented in the comment of PATH data for specific health outcomes. Significant limitations include a lack of description of the methods and statistical approach, which make it unclear how perceptions/awareness across the three waves used in the analysis were calculated and whether the longitudinal data were properly weighted. In addition, there is a lack of data from youth (younger than 18), for whom these questions were not assessed, which may potentially bias the results as younger people may be less informed about the range of health consequences caused by smoking.

Beyond concerns with the analytic approach, there are important limitations in the analysis's attempt to extrapolate from PATH survey items to the required warning topics. Many of the items used do not align well with the topic covered in the proposed warnings. For example, the specific smoking-related health effect found in the PATH item ''Based on what you know or believe, does smoking cause . . . [h]arm to fetuses (or unborn children) during pregnancy from second-hand smoke?'' is purportedly aligned with the statement ''WARNING: Smoking during pregnancy stunts fetal growth.'' Similarly, the specific smoking-related health effect found in the PATH item ''Based on what you know or believe, does smoking cause . . . [l]ung disease such as emphysema in smokers?'' is purportedly aligned with the textual statement ''WARNING: Smoking causes COPD, a lung disease that can be fatal.'' Although these PATH items may assess general awareness of related health conditions, they do not have sufficient specificity to draw conclusions about the required warnings and the particular health conditions on which they are focused. Even for items that more directly relate to the textual warning statements such as the one found for bladder cancer (''WARNING: Smoking causes bladder cancer, which can lead to bloody urine''), the PATH item ''Based on what you know or believe, does smoking cause . . . [b]ladder cancer in smokers?'' does not fully capture all information found in the required warning, such as the symptoms of bladder cancer in this example. More importantly, the PATH items do not capture information that is conveyed in the image depicting the negative health outcome, but rather only focus on one element of the warnings: The textual warning statement.

Even setting all those serious limitations aside, the evidence presented in the comment based on PATH data still show that there are significant opportunities to further promote greater public understanding of the risks associated with cigarette smoking through the required warnings. For example, even according to the comment's own analysis of PATH data, awareness among adults that smoking causes blindness (an incomplete measure of understanding that smoking causes cataracts, which can lead to blindness), was less than 50 percent, and awareness among adults that smoking causes bladder cancer was less than 60 percent. Additionally, simply being aware that smoking causes a specific health condition is not the same as understanding. As described in section V of the proposed rule (see the first paragraph of this response), understanding the negative health harms of smoking is multifaceted and comprises many processes involving attention, reading, knowledge, thinking about the risks, learning, information processing, and recall.

A more appropriate test of understanding that smoking causes the specific health conditions in the required warnings is FDA's final quantitative consumer research study (Ref. 17), which examined those specific outcomes among youth and adults and used study questions that were specific to the warnings being tested. As outlined in section VII, the individual required warnings provided new information to between 35.7 and 88.7 percent of participants in the study, and the required warnings were all perceived to be more helpful in understanding negative health effects than the current 1984 Surgeon General's warnings.

The comment also concludes that the public overestimates the risk of smoking, citing data from an academic researcher (Refs. 36 and 37). However, that research reports on surveys that were paid for and commissioned by tobacco-industry law firms in 1985, 1997, and 1998 for use in defending the tobacco industry against litigation and has been criticized on methodological and other grounds in the public health and psychology scientific literature (Ref. 38; see also, *e.g.,* Refs. 39 and 40).

2. Cigarette Health Warnings That Are Noticeable, Lead to Learning, and Increase Knowledge Will Promote Greater Public Understanding About the Negative Health Consequences of Smoking

The process of getting individuals to understand a message is a multifaceted process, as individuals must first attend to the message (*i.e.,* notice and be made aware of the message), and then they

must process the information in the message (*i.e.,* acquire knowledge of and learn that information) (Ref. 41). As FDA discussed in the proposed rule, a large body of scientific evidence demonstrates that large, pictorial cigarette warnings, such as those required in the final rule, promote greater public understanding about the health consequences of smoking as they: (1) Increase the noticeability of the warning's message, resulting in increased consumer attention to, reading, and recall of the message; and (2) increase knowledge, learning, information processing of, and thinking about the negative health consequences of smoking. Pictorial cigarette warnings address gaps in public understanding of the negative health consequences of smoking as the visual depictions of smoking-related disease in the warnings reinforce what is in the text of the warnings while also providing new information beyond what is in the text (Ref. 42; see also Ref. 43). As described in section V.B.2.c of the proposed rule, pictorial cigarette warnings can increase understanding of the negative health consequences of smoking across diverse populations while also benefitting subpopulations that have disparities in knowledge about the negative health consequences of smoking. Given the widespread implementation of large pictorial cigarette warnings on cigarette packages in over 100 countries around the world, real world experience from those countries support these conclusions. FDA received many comments on the effectiveness of large pictorial cigarette warnings in increasing public understanding of the health harms of smoking. Those comments, and FDA's responses, are summarized below.

(Comment 27) Multiple comments agree that the evidence conclusively shows that cigarette health warnings that combine images and text are more effective than text-only warnings at increasing knowledge and public understanding of the health effects of smoking. One comment, citing the 2012 Surgeon General's Report (Ref. 33), states that ''health warnings on cigarette packages are a direct, cost-effective means of communicating information on health risks of smoking to consumers'' and that such warnings increase knowledge about the harms of tobacco use. One comment notes that the scientific evidence shows that cigarette health warnings increase attention, noticeability, recall, information processing, and understanding of the warnings. The comment also states that visual depictions of smoking-related disease in pictorial cigarette warnings provide new information beyond what is found in the text of the warnings by helping to reinforce and also depict and explain the health effect in the text. The comment cites a 2008 report by the World Health Organization (WHO) (Ref. 44), which concluded that health warnings on tobacco packages increase smokers' awareness of their risk by use of pictures that depict the harms of smoking. Another comment notes that cigarette health warnings that combine images and text increase understanding of the risks of smoking by increasing attention, objective knowledge about risks, self-reported learning, and thinking about the risks of smoking.

(Response 27) FDA agrees that the scientific evidence shows that pictorial cigarette health warnings are more effective than text-only warnings at increasing knowledge and public understanding of the negative health consequences of smoking. As described in section V.B. of the proposed rule, a robust body of scientific literature shows that cigarette health warnings that combine images and text promote public understanding of the negative consequences of smoking. For example, research shows that compared to text-only cigarette warnings, pictorial cigarette warnings are more likely to be noticed (Refs. 45–57); to be read, looked at closely, and recalled (Refs. 48 and 58); to lead to higher knowledge gain and learning (Refs. 59 and 60); and to lead to thinking about the message content (Ref. 61).

(Comment 28) A comment cites a published meta-analysis (Ref. 61) of 37 studies across 16 countries that summarizes much of the current evidence base describing how cigarette health warnings that combine images and text outperform text-only warnings on outcomes such as attracting and holding attention and stronger cognitive reactions such as perceived credibility and thinking about the risks.

(Response 28) FDA appreciates the submission of this important and comprehensive research. This meta-analysis was included in the proposed rule as Ref. 50 and was discussed, along with other supportive information about the ability of pictorial cigarette warnings to improve understanding, in section V.B.2.b of the proposed rule in a subsection entitled ''Pictorial cigarette warnings increase information processing and learning of new information about the negative health consequences of smoking.''

(Comment 29) One comment from a large international tobacco research program provides an analysis of natural experiment data collected from 13 countries assessing real-world changes in adult smokers' knowledge of the health conditions—that focus on the same health conditions as those included in the proposed required warnings—before and after implementation of pictorial cigarette warnings in those countries. The comment's analysis indicates that, in all countries, there was generally no change in smokers' knowledge of already well-known health effects following implementation of pictorial cigarette warnings but that pictorial cigarette warnings can lead to further increases in knowledge of health effects for which awareness levels are already quite high. The analysis also indicated that pictorial cigarette warnings significantly improved awareness of less-known health effects and that pictorial cigarette warnings that are large and appeared on both the front and back of cigarette packs were more effective for increasing health knowledge. In addition, the comment estimates that, after the introduction of the proposed warnings in the United States, an additional 3.84 million smokers would know/be aware that smoking causes gangrene, an additional 5.22 million smokers would know/be aware that smoking causes blindness, an additional 3.22 million smokers would know/be aware that smoking causes impotence, and an additional 5.90 million smokers would know/be aware that smoking causes bladder cancer.

(Response 29) FDA appreciates the submission of this analysis of real-world data on the impact of the introduction of pictorial cigarette health warnings on smokers' knowledge of the negative health consequences of smoking. We agree that, once implemented, the required warnings will have a positive impact on the public's understanding of the negative health consequences of smoking. Indeed, in section V of the proposed rule, we discussed data (see, *e.g.,* Refs. 4, 45, 46, 61, and 62) regarding how cigarette health warnings can inform the public and lead to improvements in health knowledge by, in part, increasing noticeability of the warnings and attention paid to the warnings, and that the current 1984 Surgeon General's warnings are rarely noticed or read.

The results submitted do have some limitations that are common to real-world natural experiments, such as differences in the demographics of smokers between the countries studied and the United States. There are also some differences between the warnings in the countries studied and the final required warnings in the United States

in terms of the size of the warnings (ranging between 30 and 90 percent of the pack) and placement of the warnings (*i.e.,* on front and back of packs or just one side). Additionally, the measures used in the comment's submitted study do not match the exact wording or exact health consequences depicted in the proposed required warnings (*e.g.,* secondhand smoke causes asthma in children versus tobacco smoke can harm your children). Finally, this study only includes adult smokers, so it cannot account for the potential improvements in understanding of the negative health consequences of smoking among other nonsmoking adults or among youth.

Although there are limitations to applying evaluation findings from other countries to the United States, the evidence submitted by the comments addresses many of these limitations with its longitudinal cohort design and robust number of countries included in the analysis and as such provides a useful framework to understand the anticipated effect of the required warnings.

(Comment 30) A comment asserts that FDA failed to adequately address contrary evidence indicating that graphic warnings do not meaningfully influence consumer knowledge regarding the health consequences of smoking. The comment states that FDA ignores findings from U.S.-based studies that demonstrate little or no contribution of added color graphics to textual warning messages (Refs. 63–67).

(Response 30) In section V.B.2.a of the proposed rule, we acknowledge a small number of U.S.-based studies that failed to find that the specific pictorial cigarette warnings tested in those studies had an effect on increasing study participants' agreement with correct health beliefs about the negative effects of smoking. As we discussed in the proposed rule, the failure to find an effect may be partly or fully attributable to the fact that the public already has a high pre-existing level of knowledge of the specific health consequences described in the warnings tested in those studies, such as the nine warning statements set forth by Congress in the Tobacco Control Act that focus on better-known health consequences of smoking. Some of the comments cited recently published studies, and we have since completed review of those studies. One study (Ref. 66) compared participants who viewed pictorial cigarette warnings, based on the nine TCA statements, to those who viewed the text-only versions of the warnings. The study found that the pictorial cigarette warnings using the nine TCA statements did not promote greater public understanding when compared to text-only warnings, which is consistent with previous findings (Ref. 68). These findings are also consistent with FDA's first quantitative consumer research study, which showed that, generally, relatively few study participants reported the nine TCA statements to be new information (Ref. 12), and further support FDA's decision to develop and test new textual warning statements beyond the nine statements in the Tobacco Control Act. Finally, the comment cites additional studies that focus on the effect of pictorial cigarette warnings on emotional reactions or behavioral outcomes (*e.g.,* implicit or explicit negative evaluations) (Ref. 67), cigarette purchasing behavior (Ref. 65), quit intentions and quit attempts (Ref. 63), and smoking behaviors (Ref. 64), each of which is beyond the scope of this rulemaking. The purpose of the final rule is to promote greater public understanding of the negative health consequences of smoking.

(Comment 31) One comment questions FDA's use of existing published scientific studies from outside of the United States, which it considers unreliable scientific evidence to support the rule.

(Response 31) FDA disagrees that published scientific studies from outside the United States are, by definition, unreliable scientific evidence to support the final rule. The consistency of findings on the effectiveness of pictorial cigarette warnings across countries supports both the scientific validity and reliability of the effect of pictorial cigarette warnings, irrespective of country-specific contexts. In section V.B of the proposed rule, FDA discusses studies that demonstrate how pictorial cigarette warnings promote greater understanding about the health consequences of smoking. Some of the cited literature includes studies conducted outside of the United States. These international data are appropriate because they provide empirical support for the role of pictorial cigarette warnings in generally promoting understanding of the negative health consequences of smoking, especially as some of those studies test the effect of the actual implementation of pictorial cigarette warnings at the national level, which is not currently possible to study in the United States. Like those international studies, U.S.-based studies support the conclusion that pictorial cigarette warnings promote greater understanding of the negative health consequences of smoking. Accordingly, this body of scientific literature further confirms the findings from FDA's own consumer research studies demonstrating that the required warnings will promote greater public understanding.

(Comment 32) Some comments mention public education campaigns as an alternative to requiring cigarette manufacturers to display cigarette health warnings on their packaging and in their advertising. One comment states that FDA did not consider the potential for enhanced public education campaigns as a less burdensome approach to advance its objective and promote consumer understanding. Another comment states that ''there is also strong evidence that an FDA-run public-education campaign would be significantly more effective than the proposed graphic warnings'' and that such campaigns have several advantages over graphic warnings.

(Response 32) FDA and others have been actively engaged in a variety of public education campaigns related to cigarette and other tobacco product use, and these campaigns have made positive contributions to educating the public. However, given the enormity of the public health consequences of cigarette smoking in the United States, and the large and diverse sectors of society affected by cigarette smoking, Congress correctly concluded that this channel for communications was not by itself sufficient. Accordingly, in enacting the Tobacco Control Act, Congress amended section 4 of the FCLAA and directed FDA to issue new cigarette health warnings that include color graphics depicting the negative health consequences of smoking to accompany new textual warning statements (section 201 of the Tobacco Control Act, which amends section 4 of the FCLAA). Furthermore, research shows that cigarette packages and advertisements can serve as important channels for communicating health information to broad audiences that include both smokers and nonsmokers (Refs. 43 and 45). Daily smokers, who in 2016 averaged 14.1 cigarettes per day, are potentially exposed to the warnings on packages over 5,100 times per year, and, because these packages are often visible to individuals other than the person carrying the package, warnings on those packages are potentially viewed by many others, including nonsmokers (Refs. 43 and 69). Also, smokers and nonsmokers, including adolescents, are frequently exposed to cigarette advertising appearing in a range of marketing channels, including print and digital media, outdoor locations, and in and around retail establishments where tobacco products are sold. FDA agrees that there is an important role for other educational

efforts to inform smokers and nonsmokers about the negative health consequences of smoking; however, while such efforts complement the required warnings, they are not, by themselves, an effective alternative.

VI. FDA's Approach to Developing and Testing Cigarette Health Warnings Depicting the Negative Health Consequences of Smoking

As explained in the proposed rule, FDA undertook a rigorous science-based, iterative research process to developing and testing cigarette health warnings depicting the negative health consequences of smoking. FDA's process involved carefully reviewing the scientific literature on the health risks associated with cigarette smoking, evaluating the public's general awareness and knowledge of those health risks, and assessing the Agency's own consumer research on potential revised warning statements. Part of this iterative process included considering whether to revise the nine TCA statements to promote greater public understanding of the risks associated with cigarette smoking. FDA determined there was sufficient support to propose adjusting the text of the TCA statements, as authorized by section 4(d) of the FCLAA (as amended by section 202(b) of the Tobacco Control Act). The process also included undertaking two large consumer research studies, the second of which built on the findings from the first.

The first quantitative study was a large (2,505 participants) consumer research study to assess which, if any, of 15 revised warning statements would promote greater public understanding of the risks associated with cigarette smoking as compared to the 9 TCA statements (OMB control number 0910–0848). In this first quantitative consumer research study, each of the 9 revised textual warning statements that are included in this final rule demonstrated statistically significant higher levels on the two key measures (*i.e.,* ''new information'' and ''self-reported learning'') that are predictive for the task of identifying whether a revised warning statement will promote greater public understanding of the risks associated with cigarette smoking. The second, final quantitative study was a large (9,760 participants) consumer research study to test 16 text-and-image pairings against the current Surgeon General's warnings (OMB control number 0910–0866). We discuss the results of the final consumer research study in this section.

Both quantitative consumer research studies are described in detail in the proposed rule, along with the other steps that informed FDA's selection of the cigarette health warnings. The proposed rule also included as references the draft study reports for each quantitative study, and these reports describe the studies and present the results of the analyses from the studies. At the time the proposed rule published, the reports were undergoing peer review, and these studies have since completed peer review and are available in the docket for this final rule (Refs. 12 and 17).

A. FDA's Final Consumer Research Study Findings

FDA's final large quantitative consumer research study strongly supports the Agency's determination that the final required warnings will promote greater public understanding of the negative health consequences of cigarette smoking. The 11 final required warnings outperformed the current 1984 Surgeon General's warnings on the two outcomes FDA determined are predictive for promoting understanding of the risks associated with cigarette smoking: ''new information'' and ''self-reported learning.'' In addition, the final required warnings also demonstrated statistically significant improvement in nearly all other measures of understanding when compared to the Surgeon General's warnings.

Prior to conducting the study, FDA's study design specified that, to be considered for regulatory action, individual warnings would have to demonstrate statistically significant improvements, as compared to the current Surgeon General's warnings (which were used as the control condition), on both of two specific outcome measures: ''new information'' and ''self-reported learning'' (Ref. 204). The completed research results show that all 11 final required warnings surpassed the Surgeon General's warnings on both of these outcome measures. In addition, as the final study report demonstrates, all 11 of the final required warnings also surpassed the Surgeon General's warnings on six other measures; beyond the ''new information'' and ''self-reported learning'' outcome measures, all 11 final required warnings also led to more thinking about risks; were higher on perceived informativeness, perceived understandability, and perceived helpfulness understanding health effects; attracted more attention; and were better recalled (Ref. 17).

1. Study Design

As described in section VI.E of the proposed rule, 84 FR at 42771–72, the purpose of FDA's final quantitative consumer research study (OMB control number 0910–0866) was to assess the extent to which any of the 16 tested cigarette health warnings, developed through FDA's science-based, iterative research process, increase understanding of the negative health consequences of cigarette smoking. More details about the full study results can be found in the final peer-reviewed study report, which we have included in this docket (Ref. 17). Because the purpose of this final quantitative consumer research study was to identify which of the 16 tested cigarette health warnings increase understanding of the negative health consequences of cigarette smoking, the study was not designed to put the tested cigarette health warnings in a rank order or compare individual results of one cigarette health warning to another. FDA evaluated the research results for each individual tested cigarette health warning to determine which warnings to include in the proposed rule. In doing so, FDA rejected 3 of the 16 warnings that were tested because they did not outperform the current Surgeon General's warnings on both the ''new information'' and ''self-reported learning'' outcome measures that FDA determined are predictive of improved understanding. In finalizing the rule, FDA continued to review and evaluate the research results and has narrowed the 13 previously proposed warnings even further, down to the 11 final required warnings. Section VII provides the individual results from the final consumer research study for each of the 11 final required warnings, as well as for the 2 proposed warnings that were not selected for the final rule. We note that the study was not designed, nor statistically powered, to examine effects for various groups by age (*i.e.,* adolescent, young adult, older adults) or smoking status (*i.e.,* nonsmokers, smokers). Results are presented for the overall sample for all 10 outcome measures:

- Whether the warning was new information to participants (''new information'');
- Whether participants learned something from the warning (''self-reported learning'');
- Whether the warning made participants think about the health risks of smoking (''thinking about risks'');
- Whether the warning was perceived to be informative (''perceived informativeness'');
- Whether the warning was perceived to be understandable (''perceived understandability'');

• Whether the warning was perceived to be a fact or opinion (''perceived factualness'');

• Whether participants reported beliefs linking smoking and each of the health consequences presented in the warning (''health beliefs'');

• Whether the warning was perceived to help participants understand the negative health effects of smoking (''perceived helpfulness understanding health effects'');

• Whether the warning grabbed their attention (''attention''); and

• Whether the warning was recalled (''recall'').

Prior to conducting the study, FDA conducted a power analysis, which is a test to ensure that the overall sample size would adequately detect study effects should they exist. The power analysis allowed FDA to determine the optimal sample size and allocation of the sample across the study conditions, which informed the study sample. FDA expected it to be harder to find effects on the ''health belief'' outcome measure than on the other measures (including the ''new information'' and ''self-reported learning'' measures that FDA specified as predictive of improved understanding), and therefore powered the study on the estimated ''health belief'' effect size in order to ensure sufficient robustness to detect statistically significant differences. In particular, for the overall sample size, FDA calculated power to detect a statistically significant difference in the change in a health belief from Sessions 1 to 2 between the treatment and the control groups.

2. Use of FDA's Final Consumer Research Study Results in the Selection of Required Warnings

As discussed in section VII of the proposed rule, we identified 13 cigarette health warnings for the proposed rule. All proposed warnings were factual and accurate, advanced the Government's interest, were not unduly burdensome, and demonstrated statistically significant higher levels of providing new information and self-reported learning when compared to the control condition (*i.e.,* the Surgeon General's warnings) (Ref. 17). We stated that we intended to finalize some or all of the 13 proposed warnings and that, in determining which proposed warnings would be required in the final rule, FDA would consider public comments submitted to this docket, full research results from our final quantitative consumer research study (including peer reviewer comments), the scientific literature, and other considerations.

Since the publication of the proposed rule, FDA has continued to review and evaluate this study's results. Those results, discussed in more detail in section VII, strongly support our determination that the final required warnings will improve understanding of the negative health consequences of smoking. All 11 of the final required warnings demonstrated statistically significant improvements over the current Surgeon General's warnings (the control condition in the study) on these 8 outcomes: New information, self-reported learning, thinking about the health risks of smoking, perceived informativeness, perceived understandability, perceived helpfulness understanding health effects, attention, and recall (see Ref. 17 for more information about the study).

As described in section V.B of the proposed rule, understanding is multifaceted and composed of multiple processes. Consumer perceptions that a warning provides new information and can contribute to self-reported learning are necessary precursors to message comprehension and learning (Refs. 61, 206, and 207). An important first step in promoting public understanding of health risks is therefore to raise public awareness of those risks, particularly if the risks are not commonly known (Refs. 209 and 210). FDA determined that, to be considered for the final rule, a tested warning would need to demonstrate statistically significantly better performance than the control (the current Surgeon General's warnings) on these two ''new information'' and ''self-reported learning'' outcome measures as predictive for promoting understanding of the risks associated with cigarette smoking.

Other outcome measures were ''perceived informativeness,'' ''perceived understandability,'' ''perceived factualness,'' and ''perceived helpfulness in understanding health effects.'' These measures capture study participants' reactions to and judgment of a message (Ref. 61). In turn, an individual's judgment of a warning is linked to increased likelihood that the warning is understood (Refs. 208 and 211).

The ''health beliefs'' and ''thinking about risks'' outcome measures capture study participants' ability to process and think about the information in a message, which subsequently leads to knowledge acquisition and learning (Ref. 206). Warnings that promote accurate health beliefs and thinking about the health risks of smoking are more likely to lead to understanding about the negative health consequences of smoking compared to warnings that fail to promote these indicators.

Two other outcome measures, ''attention'' and ''recall,'' capture study participants' attention to a warning and their ability to recognize or recall the warning (Refs. 61 and 206). A warning that is noticed and attracts sufficient attention for information to be encoded and recalled increases the likelihood of understanding the warning compared to a warning that does not attract attention (Refs. 34, 207, and 208).

As noted above, all 11 final required warnings outperformed the current Surgeon General's warnings on 8 of the 10 outcome measures, including the two that FDA determined were predictive of improved understanding (*i.e.,* ''new information'' and ''self-reported learning''). On the ''health beliefs'' outcome, nearly all (9 of 11) of the final required warnings also demonstrated statistically significant improvements over the Surgeon General's warnings between Session 1 of the study and Session 2, approximately 1 to 2 days later, and many (7 of 11) of the required warnings also demonstrated statistically significant improvements over the Surgeon General's warnings on changes in health beliefs between Session 1 of the study and Session 3, approximately 17 days later. As noted in section VI.C.3 of the proposed rule, 84 FR at 42769, health beliefs may be unlikely to change with limited exposures, as was seen in FDA's first quantitative consumer research study (see Ref. 12). In FDA's final consumer research study, which had just two brief exposures to the tested warnings over 2 days, measurable changes in health beliefs were not expected (see, *e.g.,* Refs. 205 and 206). That FDA's final consumer research study found changes in health beliefs between Sessions 1 and 2 for 9 of the 11 final required warnings, and that those changes persisted for an additional 2 weeks for 7 of the 11 final required warnings, demonstrates that even with two brief exposures, the cigarette health warnings influenced participants' beliefs about the negative health consequences of smoking.

On one of the 10 outcomes in our final consumer research study, ''perceived factualness,'' the cigarette health warnings did not reliably outperform the current Surgeon General's warnings. All tested warnings (both the 16 tested cigarette health warnings and the 4 current Surgeon General's warnings, which served as the control condition) were rated as factual by the vast majority of participants. Four of the final required warnings, however, were not perceived as factual to a degree that was statistically

significantly more or less than the Surgeon General's warnings. The remaining required warnings were perceived as factual statistically significantly less than the Surgeon General's warnings. Such a finding is common in pre-implementation studies that test warnings about health effects for which there are low levels of consumer awareness (Refs. 4, 43, and 78). As explained in the responses to comments later in this section (see section VI.B.2), individuals presented with new information may view it with skepticism and even consider the new information less factual than information they have seen before (Refs. 70–77).

Beyond looking at statistical significance, FDA also considered the strength and consistency of the findings across all outcomes. Although we found some variation in the effect of each of the tested required warnings on some study outcomes, this is to be expected as there was a diverse representation of health topics across the warnings. In addition, as mentioned above and in the proposed rule, differing levels of baseline knowledge among participants about the various health conditions would contribute to the variation found in the effects across the required warnings.

In any event, the consistent pattern of findings for each individual required warning *and* across all the required warnings is highly supportive. For example, we assessed participants' ability to recall the warning they had previously been exposed to in the study. Participants viewed four warnings in random order, one of which they had previously been shown; thus, participants had a one in four (25 percent) random chance of correctly guessing the warning they had previously been shown. Participants who were shown one of the 4 Surgeon General's warnings recalled which warning they were shown at levels very similar to what they would achieve through chance guessing (25.7 percent recall). By contrast, the tested cigarette health warnings were recalled substantially more, with recall ranging from 49.4 to 73.9 percent, depending on the specific required warning.

Although not conducted with a nationally representative sample, which prevents direct extrapolation of the study findings to the U.S. population, the size and consistency of the effects found in our final consumer research study demonstrate that the required warnings will promote greater public understanding of the negative health consequences of smoking.

B. Responses to Comments Regarding FDA's Approach

FDA received numerous comments in the docket related to its approach to developing and testing new cigarette health warnings depicting the negative health consequences of smoking, which we summarize and respond to in the following paragraphs.

1. Overall Iterative Research Process

(Comment 33) Several comments support FDA's science-based, iterative research process, stating that it shows that the research was strong and demonstrates that the proposed required warnings will lead to greater public understanding of the health harms of smoking and that the proposed rule is well supported and justified. Comments note the comprehensive list of scientific references used to provide robust evidence for the support of cigarette health warnings in promoting understanding as well as the set of qualitative and quantitative consumer studies that FDA conducted. However, some comments object to the research and development process, for example, stating that FDA ''has not developed record evidence which supports the choice made,'' and that the proposed rule ''constitutes regulation on the basis of speculation, conjecture, or supposition—based on either: (1) A hypothetical reduction in smoking not supported by the record; or (2) a hypothetical problem, lack of consumer awareness of the harms of smoking.''

(Response 33) We disagree with the comments that suggest the rule is based on speculation, conjecture, and supposition. As described in detail in the proposed rule, and as many comments recognize, the rule is the result of a science-based, iterative research process across all phases of research and development of the required warnings that would advance the Government's substantial interest in promoting greater public understanding of the negative health consequences of smoking. In addition, contrary to the suggestion of at least one comment, the Government's interest in this rule is not to reduce smoking rates, but rather it is to promote greater public understanding of the negative health consequences of smoking. We discuss the Government's interest for the final rule in detail at section IV.C.1.

(Comment 34) One comment, from an internationally recognized expert in developing and testing cigarette health warnings who submitted on behalf of a public health group, summarizes and evaluates FDA's process for developing and testing the proposed required warnings, the regulatory objectives of the proposed rule, and the proposed rule's potential burden on industry. The comment ultimately concludes that FDA's regulatory objectives are clearly articulated and appropriate; FDA has engaged in a comprehensive and rigorous research process to develop and test the proposed required warnings; findings from FDA's studies highlight substantial gaps in existing health knowledge among consumers; the current 1984 Surgeon General's warnings on cigarette packages and in cigarette advertisements fall well below minimum international standards; findings from FDA's studies reinforce the importance of using graphic images to communicate the health effects of smoking; the design of the proposed required warnings is consistent with the scientific literature on effective design principles; the size of the warnings is appropriate and necessary to achieve FDA's objectives; and the proposed required warnings do not ''unduly'' restrict manufacturers' ability to convey other information on packages or advertisements. The comment further states that the findings from FDA's consumer research studies are highly consistent with the extensive evidence from ''post-implementation'' studies that have assessed the impact of pictorial cigarette warnings in other countries. The comment also considers the potential limitations that FDA identified with the studies, such as the use of an online survey and the decision made about the appropriate comparison group, and concludes that these potential limitations do not prevent the findings from providing strong support for the proposed warnings.

(Response 34) FDA agrees with this supportive comment that the research and development process was rigorous and adhered to best practices for the conduct and reporting of the studies and that the potential limitations we identified do not prevent the study findings from providing strong support for the proposed required warnings. We also agree that the studies and other scientific analysis in the proposed rule strongly support both the need for the rule as well as the ability of the rule as designed to meet the Government's objectives.

(Comment 35) At least one comment objects that FDA provided no evidence in the proposed rule to support why the Agency selected particular color graphics to illustrate the textual warning statements, including whether it considered alternative graphics to illustrate the same concepts or why it chose the selected photorealistic illustrations over others that could have

depicted the same health conditions described in the textual warning statements.

(Response 35) As described in detail in section VI.D of the proposed rule, FDA undertook an iterative, research-based approach to develop color graphics depicting the negative health consequences of cigarette smoking to accompany the textual warning statements. This process required considering findings from health communication science research regarding best practices for helping the public better understand health risk information and testing potential text statements, potential images, and potential pairings of text statements with images to ensure that the final required cigarette health warnings are unambiguous, are unlikely to be misinterpreted or misunderstood by consumers, and do convey factually accurate information.

Research indicates that multiple factors influence whether a specific type of visual depiction (such as an image compared to a bar chart or graph) ultimately aids or impedes message comprehension, including the level of concordance between the text and accompanying visual depiction (*e.g.,* using an image of an eye to depict the word ''eye''); the level of cognitive effort required to understand the information (*e.g.,* using a stacked bar chart to depict multiple data comparisons requires greater cognitive effort); and the type of communication channel used to deliver the message (*e.g.,* information presented by a doctor as part of a conversation with a patient, versus information presented in a mass media campaign) (Refs. 79–89). For example, in comparison to bar charts or graphs, visual depictions in the form of illustrations or photographs are more likely to aid comprehension when used for mass-communication purposes because these types of visual depictions are more easily made congruent (*i.e.,* the type of visual is appropriate for the message) and concordant, and they require less numerical proficiency and cognitive effort to understand the information (Refs. 81, 82, 86, and 87).

Based on our review of the literature, the cigarette health warning message content, and the communication channel, FDA determined that textual warning statements paired with factually accurate, concordant photographs or photorealistic images of specific health conditions, presented in a realistic and objective format, would be most likely to advance the Government's interest in promoting greater public understanding of the negative health consequences of cigarette smoking. FDA ultimately used a photorealistic illustration format for the images because this format best allowed FDA to ensure that the final images would be fully concordant with the ultimate textual statements addressing the same health conditions. The photorealistic illustration format also facilitated providing factually accurate images that depict common presentations of the health conditions in a realistic and objective format devoid of non-essential elements.

In terms of determining what to depict in the photorealistic illustrations, FDA consulted the medical literature and internal Agency medical experts to identify common, visual presentations of each health condition described by the textual warning statements. FDA then developed a larger set of potential warning images, which were subsequently refined and reduced, including with feedback from various qualitative focus groups and interviews, to the set of 16 text-and-image pairings that were included in the second large quantitative consumer research study.

2. Quantitative Studies

(Comment 36) One comment suggests that FDA's two quantitative consumer research studies were not credible because they did not go through a peer review process.

(Response 36) We disagree with this comment. As stated in the proposed rule, we placed in the docket for public comment two study reports that described FDA's quantitative consumer research studies and presented the results of the analyses from the studies. In developing this final rule, we considered comments on those study reports. In addition, as discussed in the proposed rule, both studies were also undergoing a peer review process, which is now complete. The peer reviewers included six experts in behavioral science (psychology, public health behavior, tobacco control/tobacco regulatory science, and health communication). The peer reviewers concluded that the studies were strong and that ''both studies are very well done in terms of design and data analysis'' and ''appropriate to address the study's purpose.'' Peer reviewers provided comments to improve the clarity of the study reports and provide additional details. The external peer review report is available on FDA's ''Completed Peer Reviews'' website at *https://www.fda.gov/science-research/peer-review-scientific-information-and-assessments/completed-peer-reviews.* Following consideration of the peer review comments, FDA updated the study reports accordingly, including adding clarifying details about the studies' procedure and analysis, but none of these updates to either study report changes the results, findings, or conclusions of either study, nor do any of the updates affect FDA's decisions that relied in part on these studies. The final peer-reviewed study reports are included in the docket to this final rule (Refs. 12 and 17).

(Comment 37) One comment asserts that FDA's two quantitative consumer research studies suffered from study design flaws and are inherently biased. The comment states that both studies compare new, more specific information in the proposed required warnings to the more general statements contained in the nine TCA statements and in the four Surgeon General's warnings. The comment argues that comparing highly detailed statements to more general statements may artificially inflate study participants' self-reported measures of learnings or new information by conflating specificity and length of the new statements with knowledge. Another comment, however, states that new knowledge among participants in the experimental conditions of FDA's studies is a logical and reasonable consequence of the potential real-world implications of displaying specific versus general health effects. Additionally, this comment states that information about specific health effects typically conveys more information and may produce more specific health knowledge, which is consistent with FDA's study findings that indicate that participants who were shown the revised textual warning statements and new cigarette health warnings reported greater scores in ''new information'' and ''self-reported learning'' when compared to the control participants.

(Response 37) FDA disagrees with the comment that the two quantitative studies suffer from design flaws and are inherently biased. Rather, as pointed out by other comments, the study design yields valid findings that exposure to the specific information contained in the required warnings promotes greater understanding of the negative consequences of smoking when compared to the broad statements contained in the warnings to which they are compared.

(Comment 38) Other comments object that FDA has not demonstrated that the required warnings will promote public understanding of the negative health consequences of smoking due to the limitations of the study measures ''new information'' and ''self-reported learning.'' One comment asserts that these study measures do not reflect increased learning and understanding

and that FDA fails to demonstrate how these measures can reflect understanding via mentally processing, reflecting on, and thinking about the harms of smoking.

(Response 38) FDA disagrees with the comment that relying on the measures of ''new information'' and ''self-reported learning'' prevent scientific support for the required warnings in advancing the Government's purpose of promoting public understanding of the negative health consequences of smoking. As described in section V.B of the proposed rule, 84 FR at 42762–65, FDA undertook an in-depth review of the scientific literature to determine that cigarette health warnings that provide new information and lead to learning promote understanding about the negative health consequences of smoking. In addition, as also described in V.B of the proposed rule, 84 FR at 42762–65, understanding is multifaceted and composed of several processes such as attention, acquiring new information, learning, knowledge, thinking about the message (*i.e.,* cognitive elaboration), and recall. FDA's final consumer research study supports the effectiveness of the required warnings in promoting understanding across these various measures, as the study's findings indicate that, overall and relative to the average of the Surgeon General's warnings (*i.e.,* the control condition), all of the new required warnings were reported to be ''new information'' and resulted in greater ''self-reported learning.'' Because the required warnings outperformed the Surgeon General's warnings on ''new information'' and ''self-reported learning''—the two outcome measures that FDA specified as predictive of improved understanding—as well as six other measures of understanding (*i.e.,* thinking about health risks of smoking, attention to the warnings, perceived informativeness, perceived understandability, perceived helpfulness in understanding health effects, recall), the study results demonstrate that the required warnings will promote greater public understanding of the negative health consequences of smoking.

(Comment 39) Some comments assert that FDA's ''new information'' and ''self-reported learning'' measures are susceptible to social desirability bias (*i.e.,* that participants respond in a way they think they ''should'' respond rather than their actual responses). However, another comment finds the measures used in FDA's consumer research studies were ''appropriate to address the research questions and have been adapted from previous research to the extent possible,'' were standardized across conditions and respondent subgroups, and where scales were created, there was sufficient rationale and details on the construction and analysis of the scales.

(Response 39) FDA disagrees that the ''new information'' and ''self-reported learning'' outcome measures in its consumer research studies are susceptible to social desirability bias, and we instead agree with the comment that the measures were appropriate to address the research conditions. As explained in the proposed rule and in the consumer research study final reports (Refs. 12 and 17), FDA reviewed the existing scientific literature on methods, design issues, and outcome measures used in other studies seeking to improve consumer knowledge and to correct misperceptions about the health risks of cigarette smoking. As we noted in the supporting statement for the information collection requests approved by the Office of Management and Budget (OMB), the measures used in both studies were drawn from previously used and/or validated instruments to ensure that instruments are not ambiguous, burdensome, or confusing (OMB control numbers 0910–0848 and 0910–0866). Finally, because of the experimental design of these studies and randomization of participants to conditions, any potential social desirability bias in participants' responses would be equally distributed among the conditions (including the control condition) thus minimizing any impact of any potential bias on the results.

(Comment 40) One comment states that FDA's final consumer research study failed to show that cigarette health warnings promote understanding due to health beliefs scores measured at Sessions 2 and 3. The comment claims that five of the warnings reduced respondents' knowledge about relevant health risks, and seven of the remaining eight warnings saw sharp decreases in knowledge gains between Sessions 2 and 3. Another comment acknowledges the challenges with changing health beliefs in study interventions with limited stimuli exposure and shorter study duration.

(Response 40) We disagree with the comment that concluded that our final consumer research study fails to show that the proposed required warnings promote understanding. Overall, the failure to detect differences in some of the outcomes assessed in the final quantitative consumer research study should be interpreted within the context of its experimental design, which collected data on 10 different measures. FDA is appropriately prioritizing the outcomes that provide the best assessment of initial reactions (''new information'' and ''self-reported learning'') over more ''delayed'' outcomes that are unlikely to change after only brief exposure to a warning (''health beliefs''). In any event, findings from the study indicate that the required warnings promote gains in health beliefs, as 11 of the 13 proposed required warnings (and 9 of the 11 final required warnings) showed greater gains in health beliefs between Sessions 1 and 2 than the Surgeon General's warnings, and, even though the study was not powered to detect changes between Sessions 1 and 3 on this measure, 7 of the 13 proposed required warnings (and 7 of the 11 final required warnings) did so. In general, health beliefs may be unlikely to change with limited exposures, as was seen in FDA's first quantitative consumer research study, which measured outcomes based on a single exposure. For FDA's final quantitative consumer research study, which only included two exposures, significant changes in health beliefs were not expected (see, *e.g.,* Refs. 205 and 206). That the final study found statistically significant changes in health beliefs between Sessions 1 and 2 for nearly all of the final required warnings, and that such changes persisted for an additional 2 weeks for 7 of them even though the study was not powered to find such changes by Session 3, demonstrates that even with limited exposure, the warnings influenced participants' beliefs about the negative health consequences of smoking.

Moreover, the conclusions made by the comment are inaccurate and misrepresent the study findings. For example, FDA is unable to find in the report or to replicate the values provided by the comment that purportedly show reductions in study participants' knowledge about health risks. FDA is similarly unable to replicate the comment's precise calculations regarding decreases in health beliefs scores between Sessions 2 and 3. In addition, as acknowledged by the other comment, there are challenges with changing health beliefs in study interventions with limited stimuli exposure and shorter study duration.

(Comment 41) A few comments state that FDA's consumer research studies fail to support the proposed required warnings, because there were instances where FDA's warnings did not improve certain outcomes measured such as ''perceived believability'' or ''perceived factualness.'' Another comment, however, observes that the inverse

association between the ''novelty'' of a health warning and its believability is a common finding in pre-implementation studies that test warnings for health effects for which consumers have low levels of awareness, citing supporting studies, and notes that the inverse association between novelty and credibility reflects the normal cognitive process that occurs when individuals integrate new information into their existing belief system. This comment notes that these findings from FDA's studies showing lower levels of perceived believability or perceived factualness should not be generalized beyond the pre-implementation settings as research shows that cigarette health warnings implemented on packages are perceived as highly credible and that the believability of new health warnings increase over time.

(Response 41) FDA disagrees with the comments that suggest the studies fail to support the proposed required warnings because there were no effects for a small number of outcomes measured, *e.g.,* ''perceived factualness.'' When individuals are presented with new information, this new information may be viewed with skepticism and perceived as less factual than information that is familiar or well-known; this finding was acknowledged by the comment speaking to the inverse association between ''novelty'' or newness of a health warning and its believability. When presented with new information, individuals may rely on certain common mental heuristics to aid judgment and decision making, though reliance on these heuristics can sometimes lead to judgment errors or biases (Refs. 70–77). Participants in FDA's consumer research studies may have relied on these types of heuristics to make judgments about the ''perceived factualness'' of the warnings tested in the study based in some measure on the ''novelty'' or newness of the new cigarette health warnings versus the familiarity of the current 1984 Surgeon General's warnings. As discussed in section V.A of the proposed rule, the Surgeon General's warnings have been displayed on cigarette packages for more than 35 years and are part of many smokers' previously held beliefs, further supporting the need to convey new information to the public that is not known about the health consequences of smoking. It is also important to emphasize that perceived factualness as measured in FDA's final consumer research study was assessed with an item telling participants, ''Next, we would like to know whether you think this warning is an opinion or a fact. Opinions are judgments or feelings that *cannot* be proven true or false. Facts are statements that *can* be proven true or false,'' and then asking participants, ''Would you say that this warning is opinion or fact?'' This outcome measure has nothing to do with the *actual* factual accuracy of the content of cigarette health warning (see earlier in this section for more discussion on our final consumer research study; Ref. 17). FDA unequivocally found that each of the warning statements is factual and uncontroversial, based on extensive scientific evidence.

(Comment 42) One comment suggests that FDA fails to address the potential for the cigarette health warnings to ''backfire'' (*e.g.,* will be avoided) and that ''highly graphic'' warnings may lower levels of recall compared to warnings with less graphic content.

(Response 42) FDA did not design the required warnings to evoke negative emotions. Rather, through the Agency's science-based, iterative research process, the required warnings were designed to be factually accurate, to make the textual statements and accompanying images depicting the specific health conditions concordant, and to present the information in a realistic and objective format (see section VII.B for further discussion of the required warnings). We disagree that the required warnings will lead to low levels of recall of the content in the warnings. To the contrary, findings from FDA's final consumer research study show that, relative to individuals who viewed the Surgeon General's warnings (*i.e.,* the control condition), individuals who viewed a cigarette health warning were much more likely to accurately recall the warning they saw.

(Comment 43) Some comments question FDA's use of non-nationally representative samples in its consumer research studies, suggesting that this limits the usefulness of the studies. Another comment, however, states that ''many non-probability based samples can provide a diverse, heterogeneous sample'' (citing Refs. 90 and 91) and ''[a]lthough participants in a commercial panel may differ from the general population, the sociodemographic profile of the FDA study sample indicates considerable diversity based on sex, education, race/ethnicity, and income level.'' In addition, this comment notes that generally, non-probability samples are acceptable for randomized trials, such as the FDA experiments. This comment concludes that overall, the study sampling designs and recruitment from both studies are appropriate for the study objectives and the analysis plan.

(Response 43) We disagree with the comments that suggest that the non-nationally representative samples used in our consumer research studies limit the usefulness of the studies in demonstrating that the required warnings will promote greater public understanding of the negative health consequences of smoking. We do agree, however, with the other comment that states that an experimental design does not require a nationally representative sample to demonstrate a valid and reliable effect. FDA set specific recruitment targets for the number of study participants in each age group and tobacco-use category to be recruited into the study population to ensure that the study results would be potentially applicable to multiple age and tobacco user groups. With respect to the study samples for Studies 1 and 2, the large heterogeneous samples allowed FDA to test outcomes across a range of individuals, thus strengthening the conclusions and applicability of the study findings, and were appropriate for the objectives of FDA's consumer research. Further, the tests of the specific textual warning statements in FDA's first quantitative consumer research study and the cigarette health warnings (*i.e.,* text plus image) in FDA's final quantitative consumer research study represent some of the largest experimental studies on cigarette warnings conducted to date.

(Comment 44) Another comment asserts that FDA's final consumer research study is flawed because FDA did not incorporate the commenter's suggestions regarding demographic and other factors in its comment submitted related to FDA's information collection request for this study. However, another comment supports FDA's study design and implementation stating that the research undertaken by FDA to inform the selection of health warnings was ''comprehensive and demonstrates a high level of scientific rigour.''

(Response 44) We disagree with the comments that suggest that the final consumer research study is flawed. While FDA considered the comments received on the information collection request for the study (OMB control number 0910–0866), including those submitted by the commenter, we did not adopt those suggestions (*e.g.,* using a nationally representative sample, changing specific study questions, changing the design to better mimic real-world conditions) as they were not necessary for the purpose of the study. FDA agrees with the comment that states that FDA's research was comprehensive and demonstrated a high level of scientific rigor due to the careful

consideration of the study design, methods, selection of measures, sampling strategy, and analysis.

(Comment 45) Some comments state that the final consumer research study suffered from methodological flaws, such as a small sample size, selection bias, a lack of meaningful pretesting, and a failure to mimic real-world conditions.

(Response 45) FDA disagrees with the criticism that our final consumer research study suffered from those methodological flaws. Regarding the sample size of 9,760 participants, prior to conducting the study, FDA conducted a power analysis, which we discuss in section VI.A.1.

Regarding the potential risk for selection bias in the final consumer research study, as stated elsewhere, FDA made efforts to ensure that the demographics of participants in the study population were diverse. Participants' demographic characteristics are reported in the final study report (Ref. 17).

With regard to meaningful pretesting, the measures used in the final consumer research study are well-established and/or pulled from validated instruments for communication and social science research focused on general health warnings or cigarette warnings, specifically. FDA reviewed studies assessing warnings for consumer products (including tobacco and cigarette health warnings), which informed the selection of the items in the proposed study.

The health belief items assess knowledge of the specific content in the warning statements. The language and wording used in these items were derived from the specific language used in the warning statements, which underwent formative, qualitative testing with adult current smokers, adolescent current smokers, and adolescents susceptible to cigarette smoking (OMB control number 0910–0674, ''Qualitative Study on Cigarettes and Smoking: Knowledge, Beliefs, and Misperceptions,'' which assessed reactions and understanding of the draft warning statements; and OMB control number 0910–0796, ''Qualitative Study on Consumer Perceptions of Cigarettes Health Warning Images,'' which assessed reactions and understanding of the draft warning statements that were paired with images). In addition, FDA evaluated the performance of questionnaire items and draft warning statements in its first large quantitative consumer research study (OMB control number 0910–0848). The findings from the aforementioned quantitative and qualitative studies informed the development of warning statements, revisions to those statements, the questions used to assess beliefs about the health condition included in the warnings, and the selection of measures for FDA's final consumer research study. In addition, the final consumer research study pretested the programmed questionnaire to assess potential programming issues that might have affected the quality of the data.

Finally, the final consumer research study was designed to increase the external validity of the study where possible. For example, the procedures for the study provided two exposures to the warnings (to better reflect frequent exposure in real-world conditions) and used a longer followup time than many similar studies to assess potential longer-term and enduring influence of cigarette health warnings to better approximate conditions once the warnings are implemented. In addition, as part of the online study, participants were able to rotate a digital mockup of a cigarette package on the screen to permit viewing all sides of the cigarette package (as opposed to viewing a static image) to better approximate real-world conditions. Participants also viewed the cigarette health warning in both formats (*i.e.,* on packages and in advertisements), which provided an appropriate presentation of the real-world display of the warnings for smokers and nonsmokers once the required warnings are implemented.

(Comment 46) One comment objects that, because FDA's final consumer research study tested the new textual warning statements and concordant photorealistic illustrations *in combination,* there is no basis to think that the ''supposed improvements'' are attributable in any way to the graphic components of the proposed required warnings, rather than to the new text.

(Response 46) We disagree with the comment's objection that ''improvements'' need to be measured separately. The purpose of the final consumer research study was to determine if new cigarette health warnings (including both text and images) would improve understanding of the negative health consequences of smoking, which the research findings do support, and is consistent with the Congress's direction that FDA issue regulations that require color graphics depicting the negative health consequences of smoking to accompany the textual warning statements. The final consumer research study's use of the current 1984 Surgeon General's warnings as the comparison is appropriate, because it allowed for investigation of the potential effect of implementing new cigarette health warnings compared to the current state of warnings for cigarette packages and advertisements in the United States. Additionally, as noted in section V.B.1 of the proposed rule, and in other comments submitted to the docket, the scientific evidence shows that larger cigarette health warnings containing text paired with images are more effective than text-only warnings at increasing knowledge and public understanding of the health effects of smoking (Refs. 4, 45–48, 54, 55, 57, 59, 61, 62, and 92–94).

(Comment 47) At least one comment states that FDA's final consumer research study fails to isolate the effect, if any, of the size and location of the warnings. The comment asserts that FDA failed to address evidence indicating that its size requirements for packaging and advertising do not advance consumer understanding. In contrast, multiple comments state that the size and location of the required warnings are appropriate and necessary to achieve FDA's objectives. These comments note that smaller, less prominent warnings on cigarette packages and in cigarette advertisements would be less effective in promoting greater public understanding of the negative health consequences of smoking. Moreover, one comment explains that ''key to the effectiveness'' of pictorial cigarette warnings is their size (taking up at least 50 percent or more of the cigarette package), text that clearly describes the health effects of smoking accompanied by a color graphic that demonstrates such negative health consequences, and placement on the front of cigarette packages. Another comment states that ''[t]he scientific evidence conclusively shows that graphic health warnings are more effective than text-only warnings at increasing knowledge and public understanding of the health effects of smoking,'' and that ''[r]esearch also shows that size plays a key role in the effectiveness of graphic warnings—larger graphic health warnings are more effective. Warnings must be large enough to be easily noticed and read, and should be as large as possible.'' Similarly, another comment gives evidence to support the necessity of the warnings in their required size and location, explaining that ''[t]he size of a health warning has an important influence on its ability to communicate health information.'' This comment also explains that the size is necessary to include important detail depicting the negative health consequences of smoking, something research on health

warnings on cigarettes and other consumer products has demonstrated consumers seek, and which increases comprehension.

Additionally, another comment from a group of health psychologists tested the impact of the proposed required warnings in their proposed size and location as compared to warnings using only the proposed textual warning statements without an image. That study reported that, compared to the text-only warnings, FDA's proposed required warnings rated higher on perceived new knowledge and understandability, providing further empirical support for the size of the required warnings. In addition, a comment submitted by another group of academics described an analysis of a longitudinal cohort survey data from 13 (non-U.S.) countries to assess changes in adult smokers' knowledge of the health effects of cigarettes before and after implementation of pictorial cigarette warnings. Pictorial cigarette warning size requirements and placement on the front and back of packages varied by country. Analysis provided by the comments concluded that pictorial cigarette warnings that are large and appeared on both the front and back of cigarette packs were more effective for increasing health knowledge.

(Response 47) We agree with the comments stating that the size and location of the required warnings on cigarette packages and in cigarette advertisements are appropriate and necessary to advance the Government's interest of promoting greater public understanding of the negative health consequences of smoking, and that the communicative value of the size and location requirements also are amply supported by evidence (see previous comment response for additional references to this body of scientific literature). Moreover, as required by section 4 of the FCLAA, as amended by the Tobacco Control Act, the required warnings must appear prominently on packages and in advertisements, occupying the top 50 percent of the area of the front and rear panels of cigarette packages and at least 20 percent of the area at the top of cigarette advertisements. As described more fully in section V.A of the proposed rule, the existing Surgeon General's warnings have been shown to go unnoticed or to fail to convey relevant information regarding the health risks of smoking, resulting in significant portions of the population that misunderstand or underestimate the health risks of smoking. The new size and location of the required warnings, as specified by statute, are needed to increase the noticeability of the required warnings in order to promote greater public understanding of the negative health consequences of smoking. The remaining 50 percent of the principal panels of product packages and the remaining 80 percent of product advertisements provide ample space for manufacturers' speech.

(Comment 48) One comment asserts that FDA failed to meaningfully address the differential effect the proposed required warnings may have on specific subpopulations. The comment states that failure to consider subgroup differences in the consumer studies can potentially impact the effectiveness of cigarette health warnings. The comment also cites research purportedly showing that cigarette health warnings lead to unintended responses among vulnerable subpopulations. Other comments, however, provide general support for the potential impact of the required warnings on socially disadvantaged groups who may possess lower knowledge of the health risks of smoking due to lower health literacy and limited access to information about the hazards of smoking. These comments state that cigarette health warnings, paired with images, depicting the harms of smoking increase the accessibility of warnings and may help to reduce disparities in health knowledge about the harms of smoking among these disadvantaged groups.

(Response 48) The purpose of FDA's two large quantitative consumer research studies was to assess whether new cigarette health warnings promote consumer understanding of the negative health consequences of smoking, not to understand the broad effects of the warnings on different populations. Although participants with various demographic and tobacco use statuses were included in the consumer research studies, the studies were not designed to examine differences in outcomes by those subgroups. The primary analyses focused on whether new cigarette health warnings increase understanding of the negative health consequences of smoking in the overall sample, and the findings support that conclusion. In exploratory subgroup analyses, findings were similar across subgroups, demonstrating the robustness of these findings.

Regarding the comment's summary of the results of scientific studies that showed a number of differential effects cigarette health warnings may have on subpopulations that vary by demographic or tobacco use statuses, none of these studies examined whether cigarette health warnings have effects on understanding of the negative health consequences of smoking. Rather, these studies examined other outcomes, including emotional reactions to the warnings, effects on intentions to quit smoking and quit attempts, and whether the warnings deter cigarette purchase, among others. Those outcomes, however, are not aligned with the Government's interest in this rule, which is to promote greater public understanding of the negative health consequences of smoking. None of the scientific studies referred to in the comment provide direct evidence suggesting that cigarette health warnings have differential effects on consumer understanding of the negative health consequences of smoking among vulnerable subpopulations. On the contrary, as described in section V.B.2.c of the proposed rule, scientific evidence suggests that pictorial cigarette warnings increase understanding of the health consequences of smoking across diverse settings and countries and are effective for diverse populations (Refs. 15, 45, 50, and 94–99), likely reducing disparities found in consumer understanding about the harms of smoking for some populations such as those with lower health literacy. For example, a study of U.S. consumers found that pictorial cigarette warnings were considered to be more attention-grabbing and more credible compared to text-only warnings; these effects were consistently observed across all subgroups, including racial/ethnic minorities, those with lower levels of education, and those with lower SES (Ref. 100). We agree with the general comments supporting the importance of the proposed required warnings and that they may help reduce disparities in health knowledge.

(Comment 49) Some comments assert that pictorial cigarette warnings do not promote greater understanding of the negative consequences of smoking. One comment cites research studies and asserts that these studies conclude that graphic warnings do not change people's beliefs about the harms of smoking.

(Response 49) FDA disagrees that pictorial cigarette warnings do not promote greater understanding of the negative health consequences of smoking. There is a substantial body of evidence to support their effectiveness. As explained in section V.B of the proposed rule, to understand a message, individuals must first attend to the message (*i.e.,* notice and be made aware of the message), and then they must process the information in the message (*i.e.,* acquire knowledge of and learn that information) (Ref. 41). These processes contribute to engagement with

the message and lead to understanding. The important role of attention in message storing and processing is well supported by research (see, *e.g.,* Ref. 101). Studies demonstrate that increasing notice of and attention to the information in a cigarette health warning promotes understanding of the message. Data from the International Tobacco Control Four Country Survey showed that noticing health warnings on cigarette packages was associated with increased knowledge about the health consequences of smoking (Ref. 4). Smokers who reported noticing the cigarette health warnings were more likely to report believing that smoking causes the specific health consequences contained in the warnings, compared to those who did not notice the warnings.

The results of FDA's final consumer research study, outlined in more detail earlier in this section, also strongly support that pictorial cigarette warnings, including the final required warnings, improve understanding of the negative health consequences of smoking. Across almost all outcomes measured in the study, the cigarette health warnings demonstrated statistically significant improvements over the Surgeon General's warnings (*i.e.,* the control condition in this study). This was true for all required warnings across the outcomes of new information, self-reported learning, thinking about the risks, perceived informativeness, perceived understandability, perceived helpfulness in understanding health effects, attention, and recall (see Ref. 17). All but 2 of the final required warnings (''harms children'' and ''COPD'' paired with an image of a man with an oxygen tank) also demonstrated statistically significant improvements over the Surgeon General's warnings on changes in health beliefs between Sessions 1 and 2; and 7 of the final required warnings also demonstrated statistically significant improvements over the Surgeon General's warnings on changes in health beliefs between Sessions 1 and 3, approximately 17 days later. As noted in section VI.C.3 of the proposed rule, health beliefs may be unlikely to change with limited exposures, as was seen in FDA's first quantitative consumer research study (see Ref. 12), which measured outcomes based on a single exposure. For FDA's final quantitative consumer research study, which only included two exposures, statistically significant changes in health beliefs also were not expected. That the final study found statistically significant changes in health beliefs between Sessions 1 and 2 for most warnings tested, and that such changes persisted for an additional 2 weeks for 7 of the warnings, demonstrates that even with limited exposure, the warnings still influenced study participants' beliefs about the negative health consequences of smoking. Another comment states, ''[t]he high threshold for changing health beliefs after brief exposure to a health warning makes the findings of [FDA's final quantitative consumer research study] all the more remarkable: brief exposure to a graphic warning led to greater changes in health beliefs after 1–2 days for 11 out of 16 warnings, and for 7 out of 16 warnings at two-week follow up.''

Finally, the comments cite studies that they assert show that pictorial cigarette warnings do not change people's beliefs about the harms of smoking. FDA has already acknowledged some of these studies in the proposed rule (see, *e.g.,* Refs. 47, 102, and 103), and, as previously discussed, we believe that the failure for the pictorial cigarette warnings tested in those studies to impact health beliefs is partly (but not entirely) due to the high preexisting knowledge of the particular smoking harms found in the warnings used in those studies (*e.g.,* many people are aware that smoking causes lung cancer). In addition, one comment cites a study (Ref. 104) that compared ''aversive'' images of health effects of smoking to ''relatively mild'' images (*e.g.,* wrinkled apple) to examine visual attention to the warnings, attitudes toward smoking, and quit intentions. That study focused on intentionally aversive images and measured attitudes and behavior, neither of which align with the design of FDA's images, the outcomes measured in FDA's consumer research study, or this rule. In part because the required warnings communicate some of the less-known and less-understood health harms of smoking, the required warnings are unlike those considered in the studies and will promote greater understanding. This view is supported by the findings of the final quantitative consumer study.

3. Qualitative Studies

(Comment 50) FDA received several comments addressing the qualitative studies.[5] Some comments suggest that the qualitative studies ''raise further questions about whether the proposed graphic health warnings will effectively improve public understanding of the health consequences of smoking.'' These comments also suggest that the qualitative study reports ''reinforce [the] position that the proposed warnings violate the First Amendment because . . . they appeal to viewers' emotions rather than conveying factual information and restrict far more speech than necessary.'' The comments point, in part, to certain statements from individual participants in the qualitative studies as evidence that the proposed required warnings being considered by FDA were confusing and misleading, and further argue that, by electing not to make the changes suggested by these individual commenters, FDA improperly ignored this evidence. The comments also point to individual statements regarding the scope of the warnings and argue that FDA ignored evidence that the proposed required warnings were broader than necessary. The comments also suggest that FDA failed to consider whether the proposed required warnings would remedy a real-world harm. The comments also suggest that FDA violated the APA by not making the qualitative study reports available when the proposed rule first issued and by providing only 15 days for public comment on these materials.

Other comments state that FDA's use of qualitative studies and related data was appropriate, noting that a key principle of qualitative research is that the analysis must look for patterns across responses, rather than rely on any one statement. One comment highlights that a potential pitfall with qualitative studies is to place ''too much emphasis on a single quote or comment that sparks interest,'' noting FDA avoided this by basing its decisions on the body of findings across the studies. Another comment notes that the qualitative studies outline the iterative, science-based process undertaken by FDA in which the findings from the qualitative studies were used to inform the development and refinement of the warnings tested in subsequent quantitative studies.

(Response 50) We agree that our use of qualitative studies was appropriate. As we discussed in the proposed rule and earlier in this section, FDA conducted various qualitative focus groups and interviews to test and refine the textual warning statements and images and to obtain feedback on which pairings of textual warning statements and images should be selected for further study. These qualitative studies are based on small sample sizes, are not nationally representative, and do not yield data that can be generalized. The intent behind conducting these qualitative studies was primarily to

[5] As discussed in section IV, the Agency supplemented the docket with qualitative study information and reopened the comment period for an additional 15 days (84 FR 60966).

explore and inform subsequent research. We disagree that a determination to not make every change suggested by individual qualitative study participants—which, in some cases, may have rendered the required warnings factually inaccurate—concedes that FDA ''ignored evidence that the proposed warnings were confusing and misleading.'' FDA did not originally include the qualitative study reports in the docket as the rulemaking itself did not directly rely on these studies. However, because the qualitative studies were used to inform further research and development, namely, the quantitative consumer research studies, FDA has made these additional materials available as well. We addressed the APA concern earlier in this document (see section IV.D.4). And, as we discuss in detail in sections IV and VII, we disagree that the required warnings violate the First Amendment.

VII. FDA's Selection of Cigarette Health Warnings

This section discusses the 11 required warnings and the factors that influenced each selection decision, including the results from FDA's final quantitative consumer research study, the substantive comments submitted to the docket, the relevant scientific literature, and other legal and policy considerations weighed, such as how well the warnings depict the negative health consequences of smoking.

When we issued the proposed rule, we proposed 13 cigarette health warnings, each comprising a textual warning statement paired with a concordant photorealistic image depicting the negative health consequences of smoking. The 13 proposed required warnings were made available as electronic files in PDF format and displayed in the document entitled ''Proposed Required Cigarette Health Warnings—PDF Files, August 2019,'' which was included in the docket for the proposed rule. Consistent with section 4 of the FCLAA, two versions of each of the 13 proposed required warnings were developed—one displaying the textual warning statement in black font on a white background, and one displaying the textual warning statement in white font on a black background.

In order to determine which of the proposed cigarette health warnings to require in the final rule, we considered a number of factors, including the results from our final consumer research study (Ref. 17; see section VI.A for a general description of the study results). We carefully examined the research results for the 13 proposed required warnings on all the different study outcomes, and we provide a discussion of those outcomes for each of the required warnings later in this section. As discussed elsewhere in this preamble, based on the results of our consumer research studies, and the existing scientific literature on cigarette health warnings, we conclude that the 11 final required warnings will advance the Government's interest of promoting greater public understanding of the negative health consequences of smoking.

We also considered the substantive public comments received in the docket related to FDA's approach to developing and testing new cigarette health warnings, including the results of our consumer research studies. We considered comments received in the docket that suggested that we use other text or images in the required warnings; however, as discussed in more detail in the comment summaries below and in section VIII, we selected the required warnings from the set of cigarette health warnings we developed, tested, and proposed. Our consumer research studies, among other information, indicate that these required warnings will promote greater public understanding of the negative health consequences of smoking. As explained in the comment responses throughout this section, the comments submitted to the docket did not persuade us that other textual warning statements or images had sufficient support to demonstrate they would advance the Government's interest in promoting greater public understanding of the negative health consequences of smoking.

A. General Comments on the Proposed Cigarette Health Warnings

FDA received several comments on the 13 proposed required warnings. Some comments discuss the 13 proposed required warnings generally, and we have summarized and responded to these comments in this section. The comments relating to each individual proposed required warning are discussed in sections VII.B and VII.C.

We considered the comments submitted to the docket as we determined which cigarette health warnings to require in the final rule. We evaluated the substantive input contained in the comments to help inform our decisions in selecting or not selecting a proposed cigarette health warning. Many of the comments contain information about the submitter's personal opinions related to various proposed warnings. While this information is helpful in understanding how some individuals might interpret various warnings and in raising issues for further exploration, this type of qualitative information is not as useful as quantitative assessments of the outcome measures related to increasing understanding, such as the evaluation provided in FDA's final consumer research study (Ref. 17).

In addition, we received a number of comments regarding our consumer research studies; these comments are summarized in section VI.

1. Comments Submitting Research on FDA's Proposed Required Warnings

We received some comments that described the results of scientific investigations that the submitters had conducted to evaluate the 13 proposed required warnings on various outcomes. We address that research and our responses to these comments in the comment summaries and responses below.

(Comment 51) One comment, representing a group of academic researchers, provides information on an experimental study conducted to evaluate responses to the 13 proposed required warnings in comparison to text-only equivalents among a convenience sample of 412 U.S. adult cigarette smokers, dual e-cigarette users and smokers, and nonusers of e-cigarettes and cigarettes. The reported findings include that: (1) Most of the proposed cigarette health warnings enhanced understandability, perceived new knowledge, worry, and discouragement to smoke relative to text-only warnings; (2) the proposed cigarette health warnings varied in their relative impact in eliciting perceived new knowledge, worry, and discouragement to smoke compared to text-only versions; and (3) effects of the proposed cigarette health warnings were generally stronger for nonusers and dual users (*i.e.,* those who both smoke cigarettes and use e-cigarettes) than for smokers, which the comments state were generally consistent with their previous work with young adults (Ref. 105). The comments conclude that these results are consistent with prior work on cigarette health warnings suggesting that such warnings enhance knowledge about the harms of smoking and evoke reactions that are associated with quitting smoking.

(Response 51) FDA appreciates the submission of this study using FDA's proposed required health warnings that demonstrates additional support for the ability of the proposed required warnings to enhance public understanding of the negative health

consequences of smoking as compared to text-only versions of the warnings. We note that one outcome included in the study referred to as ''perceived new knowledge'' is very similar to the outcome used in FDA's consumer research study referred to a ''self-reported learning'' and shows similarly strong effects on that outcome as in FDA's study. In addition, perceived new knowledge was the strongest effect of all the outcomes in the study, including worry and discouragement to use cigarettes. Overall, the study's conclusions are supported by the data presented, but there are some minor limitations in the design and measures that may limit generalizability to prior work and the general U.S. population. In addition, FDA notes that an assessment of emotional responses or behavioral study outcomes is not aligned with the final rule, whose purpose is to promote greater public understanding of the negative health consequences of smoking.

(Comment 52) Another comment from a cigarette manufacturer includes the findings of a web-based panel, created using a convenience sample, stating that the study serves as evidence that the required warnings were designed to evoke emotional negative reactions; were meant to convey an ideological anti-smoking message; and were not the less-restrictive alternative, as the study's findings purportedly show that textual warnings would be at least as effective as pictorial cigarette warnings. In the study, adult participants were randomly assigned into one of six conditions that varied in format, size, and location (*e.g.,* a text-plus-image warning on the top 50 percent of the package, a text-only warning on the top 20 percent of the package, a text-plus-image warning on the side of the package). Participants were shown a random selection of 5 of FDA's 13 proposed required warnings. Afterward, participants completed measures assessing agreement with the warning, if they had previously heard about the health effects described in the warning, if they thought the warnings were communicating that they should or should not use or purchase the product, and what message the warnings communicated. The comment's study found that, for warnings in the proposed size and location (top 50 percent of the front and rear panels of the package), between 18.9 and 65.1 percent of participants had not previously heard about the health condition in the warnings; the vast majority of participants (greater than 76.0 percent) agreed with the warning statements; and that many of the results were not different depending on the size and placement of the warnings on packages. The comment notes that the data show that many smokers in this study indicated that the warnings convey a message that they should not smoke (74 percent) or purchase the product (71 percent). The comment also reports that many smokers in this study believed the warnings are trying to make people feel disgusted (68 percent), shock people (85 percent), and make people feel distress (70 percent).

(Response 52) We appreciate the value of additional research on the potential impact of FDA's proposed required warnings, but we note that many of the outcomes assessed in this study relate to behavior and are not aligned with the final rule, whose purpose is to promote greater public understanding of the negative health consequences of smoking. The study also suffers from numerous limitations on the conclusions that can be drawn about the ability of the required warnings to promote public understanding of the negative health consequences of cigarette smoking. The limitations include that it is unclear whether each set of five warnings viewed by each participant was displayed in the same format size and location, which prevents us from drawing conclusions about the impact of size, location, and specific required cigarette warnings on outcomes relevant to understanding. Other limitations include a lack of information provided regarding sample recruitment; total sample size; study drop-out and attrition; and limited information about the sample characteristics beyond age and current smoking status. Although the comment states that the demographics of the sample were drawn to reflect the U.S. population, there is no discussion of whether the data were weighted to the U.S. population or whether the attempt to match the U.S. population was successful. While the comment includes a description of the study with some descriptive measures (*e.g.,* an appendix to the study includes the proportions), there is no information provided regarding confidence intervals or standard error; therefore, we are unable to determine the accuracy of the study's results (Refs. 106 and 107). Further, no information was provided as to whether there was adequate power to detect statistically significant differences between groups. It is unclear whether the null findings found for the effect of warnings compared to warnings with different formats is attributed to an actual lack of an effect of the cigarette health warnings or a lack of sufficient power to detect such effects (Refs. 108–110). Responses to one question only present results for 384 of the unknown total number of participants without providing information on participants who did not have an opinion on the question. The comment also did not provide information about the tobacco use status (*e.g.,* never user, former user) of half of the sample, which limits the applicability of any findings. Details were not provided about the control condition, there was no image provided of the stimuli used in that condition, and no data were provided comparing the control condition to experimental conditions. Of particular concern, it is not clear if survey items were drawn from previously validated or previously used surveys, which would lend credibility to the items used and reduce the potential for measurement error.

2. Other Comments

FDA received a number of other comments that discuss the proposed required warnings generally or highlighted issues that applied to some or all of the proposed required warnings. These comments are summarized and responded to below.

(Comment 53) Numerous comments express strong support for the proposed required warnings stating, in part, that each of the required warnings convey factual information. Comments support the 13 proposed warnings, stating that the proposed warnings cover a wide range of highly prevalent health conditions and that the health conditions are supported by a broad consensus of scientific research and Surgeon General's Reports. Other comments state that the images effectively capture attention without provoking an emotional response and the textual warning messages are brief, accurate, and clearly link to the visual image.

Some comments express support for the use of strong causal language such as ''causes,'' providing supporting scientific evidence in the required warnings, with one comment submitting a published scientific study of 1,413 adults in the United States (Ref. 111). One of these comments, which was submitted by a group of research scientists, confirms that the characteristics of FDA's proposed warnings suggest they will be effective. This comment states that FDA's proposed required warnings followed design principles and best practices in warning development that enhance their effectiveness, as follows: The warnings include human faces or diseased body parts (which, the comment notes, studies show are more effective than

other types of images); the warnings have a high degree of congruency (which, the comment notes, studies show increase recall and attention); the warnings use strong causal language; and that the warnings are concise, making the warning text easier to read and understand. Another comment from a group of scientific researchers emphasizes that the proposed warnings generally appear to contain congruent image and textual components (*i.e.,* both the image and the textual warning statement convey the same message), noting this format (congruent warning labels) is likely to be an effective means for increasing knowledge of the risks conveyed by the warnings.

(Response 53) We agree with these comments. As we describe in sections VI and VII of the proposed rule and in this section, these cigarette health warnings, as shown through robust scientific evidence, are factual and accurate and advance the substantial Government interest in promoting greater public understanding of the negative health consequences of smoking. FDA agrees that simple phrasing and the use of strong causal language in the textual warning statements is justified both by the strength of the epidemiological evidence and communication best practices.

(Comment 54) Two comments criticize nearly all the proposed required warnings for not identifying, conveying, or measuring perceptions of the baseline risk for the health conditions in the proposed required warnings. They also suggest that the absolute risk of these conditions for smokers is small and that the warnings do not convey the marginal or dose-response risk of these conditions caused by smoking, but instead misleadingly imply that the health outcomes are solely caused by smoking. The comments also state that certain warnings are misleading because they emphasize one negative health consequence rather than others with worse survival rates.

(Response 54) As described in section VII of the proposed rule, the burden of the health conditions focused on in the required warnings is substantial, and all of these health conditions are causally linked to smoking through substantial scientific evidence as summarized in various reports of the Surgeon General. Contrary to the comments' assertion, nothing in the warning text or image conveys that smoking is the only causal factor (*i.e.,* a necessary condition), nor have the comments provided any evidence to support that point. However, for many of the required warnings, smoking is one of the strongest, if not the strongest, causal factors. For example, cigarette smoking has repeatedly been identified as the most important risk factor for bladder cancer (Refs. 112–114). The National Heart, Lung, and Blood Institute of the National Institutes of Health states that smoking is a major risk factor for heart disease (Ref. 115), and the Centers for Disease Control and Prevention (CDC) states that smoking is one of the three key risk factors for heart disease (Ref. 116). FDA strongly disagrees that lack of communication about multifactorial causes of a disease in any way means that warnings that accurately state that smoking causes a negative health consequence are misleading.

The comment is correct that the marginal risk of disease attributable to smoking is not communicated as part of the warnings and thus that information is not assessed in FDA's consumer research studies. As stated in the documents related to collecting the quantitative information in FDA's consumer research studies (OMB control numbers 0910–0848 and 0910–0866) and section VI of the proposed rule, FDA's goal in the consumer research studies was to assess knowledge and understanding of a negative health outcome caused by cigarette smoking, not to educate the public about the absolute, relative, or dose-response risk conveyed by smoking. Thus, the outcomes included in FDA's consumer research studies were not intended to assess the absolute or relative level of perception of such risks, but rather investigated the effect that viewing the textual warning statements or proposed required warnings had on increasing understanding of the negative health consequences of cigarette smoking.

(Comment 55) One comment states that some of the proposed required warnings do not convey any relevant information beyond the content found in the TCA statements. In one example highlighted, the comment states that the required warning ''WARNING: Smoking can cause heart disease and strokes by clogging arteries'' conveys the exact same information as the TCA statement ''WARNING: Cigarettes cause strokes and heart disease,'' asserting that granular information about disease mechanism does not promote understanding about the health risks of smoking. In another example, the comment argues that the required warning ''WARNING: Smoking causes head and neck cancer'' conveys the same information as the TCA statement ''WARNING: Cigarettes cause cancer.''

(Response 55) FDA disagrees with both comments that some of the required warnings do not convey any relevant information beyond the content found in the TCA statements and with the conclusion that information about disease mechanism does not affect the public's understanding of the risks of smoking. For example, the required warning ''WARNING: Smoking can cause heart disease and strokes by clogging arteries'' conveys important information relevant to numerous smoking health harms: smoking causes heart disease; smoking causes strokes; smoking causes clogged arteries; and smoking causes heart disease and strokes by clogging arteries. Accordingly, all components of the required warnings, including the information related to the disease mechanism, increases public understanding of the negative consequences of smoking.

FDA also disagrees with the conclusion that providing additional information relevant to the disease (*e.g.,* ''WARNING: Smoking causes head and neck cancer'') does not improve consumer understanding above related TCA statements (*e.g.,* ''WARNING: Smoking causes cancer''). The heterogenous term ''cancer'' refers to a collection of related yet unique diseases. In this example, the required warning would promote understanding of the causal link between smoking and two different and specific cancers: Head and neck. As discussed in section V.A.3 of the proposed rule, the U.S. public is generally aware of the effects of smoking on lung cancer in smokers, while research demonstrates that the public has limited understanding of the effect of smoking on cancers outside of lung cancer. Finally, results of FDA's consumer research studies support that consumers both understand the required warnings and learn new information from them *specifically* because of the specificity of the warning used.

(Comment 56) Some comments suggest that FDA strengthen the images by making them ''less glamourous,'' more ''gross,'' or more ''shocking'' to be more in line with pictorial cigarette warnings used in other countries. One comment highlights existing research demonstrating that pictorial cigarette warnings that include ''graphic, fear-arousing depictions of the impact of smoking on the body or those that use testimonial are associated with increases in motivation to quit smoking, thinking about health risks, and engaging in cessation behavior'' (Ref. 117). Another comment suggested that use of a testimonial or image similar to ''Christine'' from CDC's ''Tips from Former Smokers'' campaign would likely evoke a much stronger emotional

response. Other comments address levels of arousal, with one comment recommending FDA drop warnings containing images with ''less arousing images [as they] will not support lasting knowledge of the associated health effects.'' One comment states that the images in the proposed required warnings are ''adequately arousing,'' citing research that shows that arousal in cigarette health warnings ''acts as information itself, a motivator, and an enhancer of information'' (Ref. 118) and that ''arousal is important for the long-term memory of the information the FDA wishes to convey'' (Ref. 119). Some comments, however, object that FDA designed the new cigarette health warnings to evoke a negative emotional response and that ''forcing'' consumers to look at the proposed required warnings ''evokes feelings of fear, shame, and disgust, and conveys the ideological message that people should not smoke.'' These comments also object that the proposed required warnings are not purely factual.

(Response 56) FDA disagrees that the images should be made more ''gross'' or ''shocking,'' and we also disagree that FDA designed the required warnings to evoke an emotional response. The images were not designed to evoke negative emotions such as fear, shame, and disgust, but rather to promote greater public understanding of the negative health consequences of cigarette smoking. As detailed in section VI.D of the proposed rule, FDA undertook a rigorous multistep process to develop, test, and refine images that: (1) Are factually accurate; (2) depict common visual presentations of the health conditions (intended to aid understanding by building on existing consumer health knowledge and experiences) and/or show disease states and symptoms as they are typically experienced; (3) present the health conditions in a realistic and objective format that is devoid of non-essential elements; and (4) are concordant with the accompanying text statements on the same health conditions. The images are not intended to evoke negative emotions such as fear, shame, and disgust, but rather to promote greater public understanding of the negative health consequences of cigarette smoking. Each of the 11 required warnings in the final rule depicts a negative health consequence of smoking that is well documented in the scientific literature. To be sure, some viewers may experience the information contained in the images—which appropriately convey the serious health consequences in a factually accurate, realistic manner—as concerning; but to the extent this occurs, it will be because the severe, life-threatening and sometimes disfiguring health effects of smoking are indeed concerning.

B. Selected Cigarette Health Warnings

This section discusses the 11 required warnings and the factors that influenced each selection decision, including the results from FDA's consumer research studies, relevant scientific literature, the substantive comments received to the docket, and other legal and policy considerations weighed. Based on these considerations, FDA has determined that the 11 required warnings included in the final rule will advance the Government's interest in promoting greater public understanding of the negative health consequences of cigarette smoking. As discussed in section VI.A of the proposed rule, the causal link between cigarette smoking and the negative health consequences depicted in each required warning is rated at the highest level of the four-level classification provided in the Surgeon General's Reports.

As described in section VI of the proposed rule, FDA undertook a science-based, iterative research and development process to develop, test, and refine new cigarette health warnings that will advance the Government's interest in promoting greater public understanding of the negative health consequences of cigarette smoking. This careful, science-based process resulted in the 11 required warnings that are the subject of the final rule. First, FDA undertook research to consider whether revisions to the textual warning statements specified in section 4(a)(1) of the FCLAA would promote greater public understanding of the risks associated with cigarette smoking. The empirical results demonstrate sufficient scientific support to adjust the textual warning statements (Ref. 12). Second, FDA carefully developed and tested concordant color graphics, in the form of photorealistic images, depicting the negative health consequences of smoking to accompany each of the textual warning statements. In FDA's final consumer research study, full cigarette health warnings—consisting of a textual warning statement paired with a concordant photorealistic image depicting the negative health consequence in the statement—were evaluated to assess the extent to which any of the warnings increase understanding of the negative health consequences of cigarette smoking. For warnings to be considered for the proposed rule, FDA decided that a warning tested in the final consumer research study must demonstrate statistically significant improvements, as compared to the control condition (*i.e.,* the Surgeon General's warnings), on both the two outcomes of ''new information'' and ''self-reported learning.''

In the proposed rule, we stated that, after considering the full results of FDA's research, the relevant scientific literature, public comments submitted to the docket, and other legal and policy considerations, FDA intended to finalize some or all of the 13 proposed cigarette health warnings. Based on the empirical results of FDA's research program, as well as our consideration of each of the factors discussed in this section, FDA is including the following 11 required warnings in the final rule. Because these required warnings, as shown through the robust scientific evidence described in detail in sections VI and VII of the proposed rule, are factual and accurate, advance the Government's interest in promoting greater public understanding of the negative health consequences of cigarette smoking, and are not unduly burdensome (see section IV.B for a more detailed discussion), FDA believes the required warnings are consistent with the First Amendment, regardless of the standard of scrutiny (*e.g., Zauderer* or *Central Hudson*) under which they are reviewed.

The required warnings, each of which consists of a textual warning statement paired with a concordant photorealistic image depicting the negative health consequences of smoking, are contained in a document entitled ''Required Cigarette Health Warnings, 2020'' (Ref. 11), as is further discussed in section III.B.

With regard to the photorealistic images contained in the required warnings, and as described in section VI.D of the proposed rule, FDA undertook a rigorous multistep process to develop, test, and refine images that: (1) Are factually accurate; (2) depict common visual presentations of the health conditions (intended to aid understanding by building on existing consumer health knowledge and experiences) and/or show disease states and symptoms as they are typically experienced; (3) present the health conditions in a realistic and objective format that is devoid of non-essential elements; and (4) are concordant with the accompanying text statements on the same health conditions.

FDA considered many different factors when developing the warning images, including current public understanding and gaps in knowledge of the negative health consequences of

cigarette smoking; the varied levels of health literacy and numeracy among the U.S. population; findings from communication science research regarding the types of visual depictions that are most appropriate for communicating health risk information to lay audiences; general best practices for developing mass communication efforts; the Agency's statutory requirements for cigarette health warnings under section 4 of the FCLAA (as amended by sections 201 and 202 of the Tobacco Control Act); and the practical implications of visually depicting the negative health consequences of cigarette smoking in the form of warnings on cigarette packages and in advertisements.

As a form of mass communication, cigarette health warnings must feature messages that are appropriate for the target audience, communication channel, and public health goals. In section VI of the proposed rule, we described the process for developing and testing the required cigarette warnings in detail, outlining the health communication science research findings we considered when determining how best to help promote greater public understanding of the negative health consequences of cigarette smoking. For example, the American public is a diverse population comprising individuals with many varied backgrounds, knowledge, beliefs, and abilities to read and understand health information. In fact, national surveys indicate that only about 12 percent of U.S. adults have proficient health literacy (*i.e.,* the ability to access, understand, and use health information and services) and fewer than 10 percent have proficient numeracy levels (*i.e.,* the ability to understand and use numbers, including the ability to read and interpret data presented in tables, graphs, and bar charts (Refs. 120–123). Considering these differences in health literacy and numeracy levels, as well as additional factors such as the limited amount of space for additional explanatory text and graphics and the constraints of a one-way communication channel, attempting to convey complex information such as quantitative risk measures would be incongruent with the Government's interest of increasing public understanding of the negative health consequences of cigarette smoking. Instead, best practices for health risk communication state that simple, clear, and direct messages are best understood, especially for those with low health literacy and numeracy.

Further, given the need to visually depict the content of the required warning's textual warning statements with concordant, factually accurate color graphics that promote greater understanding of the health consequences as described by the text, the majority of images appropriately depict external symptoms and disease states. FDA hired a certified medical illustrator to develop—in close collaboration with FDA staff—the high-quality, factual, medically accurate, photorealistic images. As explained in section VI.D of the proposed rule, FDA determined that photorealistic illustrations would be the most appropriate visual depiction format because this format best allowed depicting specific features of the health conditions as described by the textual warning statements. The photorealistic illustration format also facilitated providing factually accurate images that depict common presentations of the health conditions in a realistic and objective format devoid of non-essential elements. Using photorealistic images also allowed further editing and refinements for clarity and ease of understanding throughout the science-based, iterative research and development process for new cigarette health warnings.

The photorealistic images in these required warnings present the health conditions in a realistic and objective format, do not contain additional unnecessary details, and do not contain any elements intended to evoke a negative emotional response. Because these warnings are designed to educate the public about the very real, serious, and sometimes deadly outcomes of cigarette smoking, the factually accurate content may evoke subjective, emotional responses among some consumers based on their personal history and personality characteristics. See section IV.C.2.b for a discussion of comments on this topic.

In this section's discussion of the results from our final consumer research study for each required warning, a study effect with an associated p-value below 0.05 (or $p<0.05$) is considered to be a ''statistically significant'' effect. A p-value is reflective of the probability that a study finding could have happened by chance. For example, a p-value of 0.04 means that if there was no true study effect, the observed finding would still be obtained in 4 percent of studies due to chance. Having a predetermined cut off at $p<0.05$ is a commonly used level to conclude the effect has a very low likelihood of being due to chance. In our analyses, we also use additional statistical controls (Refs. 124 and 125) to account for the number of different statistical tests computed across all warnings for all outcomes. With an increased number of statistical tests performed, more findings could happen by chance alone. Controlling for this helps to produce estimates of statistical significance that are more conservative and produce higher confidence in the results. The full description of our final consumer research study and the analyses are contained in the final, peer-reviewed study report (Ref. 17).

We describe each of the required warnings next, along with a summary of comments received and FDA's responses.

1. ''WARNING: Tobacco smoke can harm your children.''

This required warning consists of the TCA statement ''WARNING: Tobacco smoke can harm your children'' paired with a concordant, factually accurate, photorealistic image depicting a negative health consequence of secondhand smoke exposure in children. The image shows the head and shoulders of a young boy (aged 8–10 years) wearing a hospital gown and receiving a nebulizer treatment for chronic asthma resulting from secondhand smoke exposure.

In FDA's final consumer research study, this warning was reported to be new information by 40.7 percent of participants who viewed it. In section VI of the proposed rule, we explained that the two outcomes of ''new information'' and ''self-reported learning'' are predictive of whether new cigarette health warnings increase understanding of the risks associated with cigarette smoking. Compared to the average of the ratings for the four Surgeon General's warnings (the control condition in the study), this warning was statistically significantly ($p<0.05$, after adjusting for age group, smoking status, and multiple comparisons) higher on both providing new information and self-reported learning. In addition, this warning was statistically significantly higher than the Surgeon General's warnings on nearly all other outcomes measured. This warning grabbed attention more, resulted in more thinking about the risks, and was perceived to be more informative, to be more understandable, and to be more helpful in understanding the health effects of smoking. The warning was correctly recalled by 61.6 percent of participants, which was statistically significantly higher than the 25.7 percent who recalled the Surgeon General's warnings.

Most participants (83.1 percent) perceived the warning to be factual, a result that was not statistically different from the Surgeon General's warnings. Despite the strong results on nearly all

other measures includes in the study, this warning did not show statistically significant improvements in health beliefs either between Sessions 1 and 2 or between Sessions 1 and 3 over the changes in participants who viewed the Surgeon General's warnings, which is not surprising given the relatively brief exposure to the warning. Full details of the results for this warning in FDA's final consumer research study are available in the study's final report (Ref. 17).

We received a number of comments on this warning, which we have summarized and responded to below.

(Comment 57) Multiple comments support the inclusion of this warning in the final rule, with one comment emphasizing the importance of messages that reinforce the causal link between secondhand smoke exposure and negative health outcomes in children (*e.g.,* impaired lung function, asthma and respiratory illnesses, sudden infant death syndrome, other preventable childhood illnesses).

(Response 57) We agree that this cigarette health warning is important, focuses on a serious health risk of smoking, and will promote greater public understanding of the negative health consequences of smoking.

(Comment 58) Some comments object to this warning because they assert it is inaccurate and misleading in a number of respects. One comment questions the epidemiological evidence used to support this warning, stating that the evidence does not support the causal relationship between parental secondhand smoke and either ''chronic asthma'' or asthma attacks in children ''requiring nebulizer treatment.'' Another comment states that the image does not convey purely factual information because ''[n]o reasonable consumer would be able to determine from the image'' that the child depicted has chronic asthma from secondhand smoke exposure or is receiving a nebulizer treatment. Rather, the comment states that the child's appearance and the mask over the child's face ''suggest only that the child is experiencing a medical emergency that requires receipt of oxygen.'' Some comments assert that the proposed warning is ''ambiguous,'' because it appears to depict the administration of oxygen following an asthma attack, and is an ''exaggerated'' or ''worst case scenario'' treatment for an asthma attack, because it is uncommon for a child with an asthma attack to require oxygen or to be hospitalized. One comment states that the text and image are not concordant, because the general description of a child suffering harm is not clarified by the picture, and the ''ambiguity regarding the harm at issue adds to the fear and confusion a consumer would experience when viewing the warnings.'' Finally, one comment states that the proposed warning ''seeks to advance FDA's anti-smoking message'' by evoking an emotional response in consumers, because adults viewing the image would be ''horrified at the thought of inflicting such harm on their children.''

(Response 58) We disagree with comments suggesting that this warning is inaccurate or misleading. As explained at length in section VI of the proposed rule, FDA undertook a rigorous, multistep process to develop, test, and refine the textual warning statement, accompanying image, and the overall warning.

The textual warning statement ''WARNING: Tobacco smoke can harm your children'' is factually accurate. Tobacco smoke exposure in children is causally linked to numerous negative health consequences, including several respiratory illnesses (Refs. 3 and 126). As stated in section VII.A.1 of the proposed rule, the 2006 Surgeon General's Report on the health effects of involuntary exposure to tobacco smoke concludes that ''the evidence is sufficient to infer a causal relationship between secondhand smoke exposure from parental smoking and lower respiratory illnesses in infants and children''; ''the evidence is sufficient to infer a causal relationship between parental smoking and cough, phlegm, wheeze, and breathlessness among children of school age''; ''the evidence is sufficient to infer a causal relationship between parental smoking and ever having asthma among children of school age''; and ''the evidence is sufficient to infer a causal relationship between secondhand smoke exposure from parental smoking and the onset of wheeze illnesses in early childhood'' (Ref. 126). The report also concludes that ''the evidence is sufficient to infer a causal relationship between maternal smoking during pregnancy and persistent adverse effects on lung function across childhood'' and ''the evidence is sufficient to infer a causal relationship between exposure to secondhand smoke after birth and a lower level of lung function during childhood.'' As noted in the proposed rule, more recent studies also support these same conclusions (see, *e.g.,* Ref. 127).

Additionally, the image in the warning is factually accurate and depicts a common visual presentation of this negative health consequence. The child has features consistent with chronic asthma (*e.g.,* ''allergic shiners'' under the eyes), is wearing a hospital gown, and is holding a nebulizer mask. Tobacco smoke exposure can cause children who already have asthma to experience more frequent and severe asthma attacks (Ref. 126). A retrospective review of hospital-based data examining secondhand smoke exposure and asthma severity among children with asthma presenting to the pediatric emergency department (PED) showed more severe presentation and greater resource utilization in the PED for secondhand smoke-exposed children (Ref. 128). Additionally, a systematic review found that children with asthma and secondhand smoke exposure are nearly twice as likely to be hospitalized with asthma exacerbations compared to children with asthma but without secondhand smoke exposure (Ref. 129). Further, acute asthma exacerbations can be severe and may necessitate treatment, including nebulizer treatment, in an emergency department or an inpatient setting. Therefore, this image depicts a factually accurate, common visual presentation of the health condition and shows the disease state as it is typically experienced.

Further, the textual warning statement and image are concordant, and the warning is not ambiguous. The textual warning statement explains that tobacco smoke can harm children. The accompanying concordant and factually accurate image depicts a child who has been harmed by tobacco smoke exposure. As stated in the preceding paragraph, it is not rare or atypical for children with chronic asthma resulting from secondhand smoke exposure to receive nebulizer treatments in either an emergency department or inpatient setting. Because the required warning contains the textual warning statement and image paired together, the image aids in understanding the negative health consequence that is the focus of the textual warning statement, and vice versa.

Finally, we disagree with the assertion that the image is intended to evoke an emotional response. The image presents the health condition in a realistic and objective format, does not contain additional unnecessary details (*e.g.,* hospital room setting, other medical equipment), and does not contain any elements intended to evoke a negative emotional response.

2. ''WARNING: Tobacco smoke causes fatal lung disease in Nonsmokers.''

This required warning consists of the TCA statement ''WARNING: Tobacco smoke causes fatal lung disease in nonsmokers'' paired with a concordant, factually accurate, photorealistic image

depicting fatal lung disease. The image shows gloved hands holding a pair of diseased lungs containing cancerous lesions from chronic secondhand smoke exposure.

In FDA's final consumer research study, this warning was reported to be new information by 41.9 percent of participants who viewed it. In section VI of the proposed rule, we explained that the two outcomes of ''new information'' and ''self-reported learning'' are predictive of whether new cigarette health warnings increase understanding of the risks associated with cigarette smoking. Compared to the average of the ratings for the four Surgeon General's warnings (the control condition in the study), this warning was statistically significantly ($p<0.05$, after adjusting for age group, smoking status, and multiple comparisons) higher on both providing new information and self-reported learning. In addition, this warning was statistically significantly higher than the Surgeon General's warnings on nearly all other outcomes measured. This warning grabbed attention more, resulted in more thinking about the risks, and was perceived to be more informative, to be more understandable, and to be more helpful in understanding the health effects of smoking. The warning was correctly recalled by 66.7 percent of participants, which was statistically significantly higher than the 25.7 percent who recalled the Surgeon General's warnings.

Most participants (77.5 percent) perceived the warning to be factual, a result that was statistically significantly lower than the control condition. Participants who viewed this warning showed statistically significant improvements in their health beliefs between both Sessions 1 and 2 and Sessions 1 and 3 as compared to the changes in participants who viewed the Surgeon General's warnings. Full details of the results for this warning in FDA's final consumer research study are available in the study's final report (Ref. 17).

We received a number of comments on this warning, which we have summarized and responded to below.

(Comment 59) Some comments object to this warning because they assert it is inaccurate and misleading. For example, one comment states the image does not convey purely factual information because it does not clarify the types of lung disease nonsmokers may experience, and it is not clear that a layperson would understand that the lungs are diseased and contain cancerous lesions.

Some comments also state that the illustration does not accurately depict the lungs of ''the rare never smoker who suffers from fatal lung disease due to secondhand smoke'' and that the lungs ''do not look like a non-smoker's lungs'' due to the amount of pigmentation and the appearance of the lesions on the lungs (*i.e.,* because such lesions would not appear on the surface of the lung and it would be unusual to have three separate lesions of the size depicted). The comments also suggest that FDA acknowledges in the proposed rule that the lung depicted is similar to the lungs of a smoker with COPD.

Another comment suggests that the warning is misleading because it emphasizes a condition that is less prevalent than other smoking-attributable health conditions. This comment also suggests that the proposed warning ''seeks to advance FDA's anti-smoking message'' by evoking an emotional response in consumers because the image of ''blood-covered hands holding bloody diseased lungs from a deceased individual is intended to shock and disturb viewers with its goriness or to generate fear about the prospect of death and having one's lungs removed postmortem.''

(Response 59) We disagree with comments suggesting that this warning is inaccurate or misleading. As explained at length in the proposed rule, FDA undertook a rigorous, multistep process to develop, test, and refine the textual warning statement, accompanying image, and the overall warning.

The textual warning statement ''WARNING: Tobacco smoke causes fatal lung disease in nonsmokers'' is factually accurate. As stated in the proposed rule, the 1986 and subsequent Surgeon General's Reports have confirmed the causal link between secondhand smoke exposure and lung cancer, a fatal lung disease, among nonsmokers (Refs. 126 and 130). The conclusion in the 2006 Surgeon General's Report extends this conclusion to all secondhand smoke exposure, regardless of location of exposure (*e.g.,* at home, at work, in other settings); the combined evidence from multiple studies indicates a 20 to 30 percent increase in the risk of lung cancer from secondhand smoke exposure associated with living with a smoker (Ref. 126). For example, a meta-analysis of 43 studies, including studies conducted both in the United States and outside of the United States, found that the relative risk of lung cancer among nonsmoking women who live with partners who smoke (*i.e.,* the risk of the lung cancer among nonsmokers living with smokers compared to nonsmokers not living with smokers) was 1.29 (Ref. 131). This means that nonsmoking women who live with partners who smoke have 1.29 times higher risk of lung cancer compared to nonsmoking women who live with partners who do not smoke. Recent studies support and extend these conclusions (Refs. 132–135).

Additionally, the image in the warning is factually accurate and depicts a common visual presentation of this negative health consequence. The lungs are clearly postmortem, as they have been removed from the patient's body, and the cancerous lesions and discoloration caused by vascular congestion (*i.e.,* blood in the lower lungs causing a darker coloration) are consistent with the appearance of postmortem lungs in a nonsmoking patient with fatal lung disease.

Tobacco smoke is carcinogenic. Unlike lung cancer in smokers, lung cancer in nonsmokers targets the distal airways (Ref. 136) and is more likely to appear as depicted in the warning (*i.e.,* discolored or darkened in the lower lungs). In comparison, postmortem lungs of a smoker would typically have a darker, almost black, coloration in the medial lungs (*i.e.,* middle of the lungs, facing the chest) as well as other visible features that are not depicted in this image of a nonsmoker's diseased lungs. Therefore, this image depicts a factually accurate, common visual presentation of the health condition and shows the disease state as it is typically experienced.

Further, the textual warning statement and image are concordant, and the warning is not ambiguous. The textual warning statement explains that tobacco smoke can cause fatal lung disease in nonsmokers. The accompanying concordant and factually accurate image appropriately depicts the postmortem lungs of a nonsmoker with fatal lung disease. Because the required warning contains the textual warning statement and image paired together, the image aids in understanding the negative health consequence that is the focus of the textual warning statement, and vice versa.

Finally, we disagree with the assertion that the image is intended to evoke an emotional response. The image presents the health condition in a realistic and objective format, does not contain additional unnecessary details (*e.g.,* surgical tools used to remove the lungs, background setting), and does not contain any elements intended to evoke a negative emotional response.

3. ''WARNING: Smoking causes head and neck cancer.''

This required warning consists of the textual warning statement ''WARNING: Smoking causes head and neck cancer'' paired with a concordant, factually accurate, photorealistic image depicting neck cancer. The image shows the head and neck of a woman (aged 50–60 years) who has neck cancer caused by cigarette smoking. The woman has a visible tumor protruding from the right side of her neck just below her jawline.

In FDA's final consumer research study, this warning was reported to be new information by 80.9 percent of participants who viewed it. In the proposed rule, we explained that the two outcomes of ''new information'' and ''self-reported learning'' are predictive of whether new cigarette health warnings increase understanding of the risks associated with cigarette smoking. Compared to the average of the ratings for the four Surgeon General's warnings (the control condition in the study), this warning was statistically significantly ($p<0.05$, after adjusting for age group, smoking status, and multiple comparisons) higher on both providing new information and self-reported learning. In addition, this warning was statistically significantly higher than the Surgeon General's warnings on nearly all other outcomes measured. This warning grabbed attention more, resulted in more thinking about the risks, and was perceived to be more informative, to be more understandable, and to be more helpful in understanding the health effects of smoking. The warning was correctly recalled by 58.1 percent of participants, which was statistically significantly higher than the 25.7 percent who recalled the Surgeon General's warnings.

Most participants (71.6 percent) perceived the warning to be factual, a result that was statistically significantly lower than the control condition (see section VI for a fuller discussion of the ''perceived factualness'' outcome). Participants who viewed this warning showed statistically significant improvements in their health beliefs between both Sessions 1 and 2 and Sessions 1 and 3 as compared to the changes in participants who viewed the Surgeon General's warnings. Full details of the results for this warning in FDA's final consumer research study are available in the study's final report (Ref. 17).

We received a number of comments on this warning, which we have summarized and responded to below.

(Comment 60) Some comments object to this proposed warning because they assert it is inaccurate and misleading in a number of respects. For example, one comment asserts that the image depicts an ''exceedingly rare'' outcome in terms of tumor size and quotes another comment that states the image implies that ''a cancerous mass of that size could arise quickly enough that a reasonable person would not have had an opportunity to seek treatment before this point.'' Another comment states that on its own, the image does not convey purely factual information, because it is not obvious whether the growth is a tumor or something else. One comment states the proposed warning ''seeks to advance FDA's anti-smoking message'' by evoking an emotional response in consumers because ''the image of a woman with a large tumor protruding from her neck is disturbing and unsightly and is clearly designed to provoke disgust or discomfort at the sight of the image, fear at the prospect of experiencing the same uncomfortable medical condition, or both.''

Many other comments support the inclusion of this warning in the final rule. One comment supporting the inclusion of the warning states that an estimated 53,000 new cases of cancers of the oral cavity and pharynx, which are types of head and neck cancer, will be diagnosed in 2019 and over 10,000 people will die from those cancers this year and that tobacco use is a major risk factor for these cancers (Ref. 137). Another comment provided a summary of the 1964 through 2010 Surgeon General's Reports as demonstrating strong evidence for the association between smoking and head and neck cancer.

(Response 60) We disagree with comments suggesting that this warning is inaccurate or misleading. As explained at length in the proposed rule, FDA undertook a rigorous, multistep process to develop, test, and refine the textual warning statement, accompanying image, and the overall warning.

The textual warning statement ''WARNING: Smoking causes head and neck cancer'' is factually accurate. As many comments note, there is strong scientific support for the causal link between smoking and head and neck cancer. For example, and as described in the proposed rule (see section VII.A.3 of the proposed rule), the 2004 Surgeon General's Report stated that the evidence is sufficient to infer a causal relationship—the highest level of evidence of causal inferences from the criteria applied in the Surgeon General's Reports—between smoking and cancers of the oral cavity, pharynx, and larynx (Ref. 138), building on the strong conclusions of causality from previous reports. A more recent study (Ref. 139), submitted in a comment, that pooled data from 23 studies, found that those who smoked >0 to 3 cigarettes per day had 52 percent increased odds of head and neck cancer compared to never smokers. Those who smoked >3 to 5 cigarettes per day had 2.01 to 2.74 times the odds of head and neck cancer as compared to never smokers.

Additionally, the image in the warning is factually accurate and depicts a common visual presentation of this negative health consequence. The location (*i.e.,* on the neck, under the jawline) and appearance of the tumor in a woman of the age pictured (50–60 years) is suggestive of a cervical lymph node metastasis (*i.e.,* cancer in a lymph node) (Refs. 140 and 141). Cancers of the head and neck commonly metastasize to the cervical lymph nodes; therefore, the image is entirely consistent with a diagnosis of head and neck cancer (Ref. 142). Moreover, the image is very similar to other images easily found depicting the same health condition (Ref. 140 at Figure 3 and Ref. 143 at Figure 1a). Although some comments assert this image is misleading because ''there would be other signs of the cancer before the patient would develop a metastasis of the size and presentation in the proposed graphic,'' this assertion is not accurate as not all patients with cervical lymph node metastases have other symptoms. It is not unusual for cervical lymph node metastasis to be the first symptom of head and neck carcinoma that causes the patient to seek treatment (Ref. 144 at Chapter 9).

Some comments also claim that the image is misleading because it suggests that ''a cancerous mass of that size could arise quickly enough that a reasonable person would not have had an opportunity to seek treatment before this point.'' Despite experiencing early symptoms for head and neck cancer, some individuals may not be able to seek early cancer screening and detection, resulting in diagnosis only when the disease has become advanced. Factors such as lack of health insurance coverage, lack of financial resources, lack of transportation, and lack of cancer knowledge serve as barriers to cancer screening, resulting in late-stage diagnosis for head and neck cancer (Refs. 143 and 146). As a result, it is not unusual for patients from underserved communities to present at advanced stages for head and neck cancer as depicted in the warning's image (Ref. 143 at Figure 1a and Ref. 147). Therefore, this image depicts a factually accurate, common visual presentation of the health condition.

Further, the textual warning statement and image are concordant, and the warning is not ambiguous. The textual warning statement explains that smoking causes head and neck cancer. The accompanying concordant and factually accurate image depicts the head and neck of woman (aged 50–60 years) who has a cancerous growth protruding from her neck below her jawline. Because the required warning contains the textual warning statement and image paired together, the image aids in understanding the negative health consequence that is the focus of the textual warning statement, and vice versa.

Finally, we disagree with the assertion that the image is intended to evoke an emotional response. The image presents the health condition in a realistic and objective format, does not contain additional unnecessary details (*e.g.,* background setting), and does not contain any elements intended to evoke a negative emotional response.

4. ''WARNING: Smoking causes bladder cancer, which can lead to bloody urine.''

This required warning consists of the textual warning statement ''WARNING: Smoking causes bladder cancer, which can lead to bloody urine'' paired with a concordant, factually accurate, photorealistic image depicting bloody urine. The image shows a gloved hand holding a urine specimen cup containing bloody urine resulting from bladder cancer caused by cigarette smoking.

In FDA's final consumer research study, this warning was reported to be new information by 87.2 percent of participants who viewed it. In the proposed rule, we explained that the two outcomes of ''new information'' and ''self-reported learning'' are predictive of whether new cigarette health warnings increase understanding of the risks associated with cigarette smoking. Compared to the average of the ratings for the four Surgeon General's warnings (the control condition in the study), this warning was statistically significantly ($p<0.05$, after adjusting for age group, smoking status, and multiple comparisons) higher on both providing new information and self-reported learning. In addition, this warning was statistically significantly higher than the Surgeon General's warnings on nearly all other outcomes measured. This warning grabbed attention more, resulted in more thinking about the risks, and was perceived to be more informative, to be more understandable, and to be more helpful in understanding the health effects of smoking. The warning was correctly recalled by 57.8 percent of participants, which was statistically significantly higher than the 25.7 percent who recalled the Surgeon General's warnings.

Most participants (66.0 percent) perceived the warning to be factual, a result that was statistically significantly lower than the control condition (see section VI for a fuller discussion of the ''perceived factualness'' outcome). Participants who viewed this warning showed statistically significant improvements in their health beliefs between both Sessions 1 and 2 and Sessions 1 and 3 as compared to the changes in participants who viewed the Surgeon General's warnings. Full details of the results for this warning in FDA's final consumer research study are available in the study's final report (Ref. 17).

We received a number of comments on this warning, which we have summarized and responded to below.

(Comment 61) Some comments object to this proposed warning because they assert it is inaccurate and misleading. For example, one comment states that the proposed warning is misleading because it suggests that bloody urine is a more serious health concern than bladder cancer. One comment suggests that, on its own, the image does not convey purely factual information because a consumer would not be able to determine from the image alone that the liquid depicted is bloody urine or bloody urine resulting from bladder cancer. This comment also asserts that the text and image are not concordant because nothing about the picture indicates that bladder cancer is the subject of the warning.

Some comments suggest that the textual warning statement may be misleading and recommend revisions. For example, one comment suggests changing ''can'' to ''may'' or adding a disclaimer that ''bladder cancer is not the only cause of bloody urine'' and/or ''the absence of bloody urine does not mean the absence of bladder cancer.'' Another comment suggests that the proposed warning may be misleading because it understates the possible negative health consequences and recommends that the textual warning statement say, ''Smoking causes bladder cancer, which can lead to removal of part or all of the bladder.''

Other comments suggest changes to the image, such as using a different image because the proposed image does not depict a body part or a human face. Another comment recommends making the image of the urine cup more clear by labeling the cup with words such as ''urine sample'' and darkening the color to a red resembling the color of blood.

Finally, one comment states the proposed warning ''seeks to advance FDA's anti-smoking message'' by evoking an emotional response in consumers because the image ''appears designed to provoke an emotional reaction of fear or disgust regarding the nature of the depicted liquid.''

(Response 61) We disagree with comments suggesting that this warning is inaccurate or misleading. As explained at length in the proposed rule, FDA undertook a rigorous, multistep process to develop, test, and refine the textual warning statement, accompanying image, and the overall warning.

The textual warning statement ''WARNING: Smoking causes bladder cancer, which can lead to bloody urine'' is factually accurate, and we decline to make changes to the text. As explained in the proposed rule (see section VII.A.4 of the proposed rule), smoking is a strong causal factor in the development of bladder cancer. Recent research illustrates that even smoking a few cigarettes per day is associated with an increased risk of bladder cancer (Ref. 148), and the CDC estimates that 40 percent of bladder cancer *deaths* (not bladder cancer cases, as one comment asserts) from 2000 through 2004 were attributable to smoking, representing almost 5,000 deaths per year (Ref. 149). Cigarette smoking has repeatedly been identified as the most important risk factor for bladder cancer (Refs. 112–114).

Additionally, the image in the warning is factually accurate and depicts a common visual presentation of this negative health consequence. As stated in the proposed rule, in most cases, blood in the urine (called hematuria) is the first visible sign of bladder cancer (Ref. 150). The Mayo Clinic notes that hematuria results in urine that can be pink, red, or brown/cola-colored (Ref. 151). The current color depicted in the image is factually accurate, and a darker red may lead to confusion as to whether the liquid contains only blood or bloody urine. We also decline to add a qualifying label to the specimen cup that says ''URINE SPECIMEN'' as the specimen cup with a gloved hand depicts a routine sampling procedure typical in laboratory testing and medical processing of biological samples. Further, the image is already paired with a textual warning statement indicating the cup contains urine. Therefore, this image depicts a factually accurate, common visual presentation of the health condition and shows a symptom of the disease state as it is typically experienced.

Further, the textual warning statement and image are concordant, and the warning is not ambiguous. We disagree with comments suggesting the warning is misleading or ineffective because it understates the possible negative health consequences for this health condition; does not depict a body part or face; or does not include information not directly focused on the specific warning, such as the possibility of bladder cancer occurring in the absence of bloody urine or the possibility of other nonsmoking-related causes of bloody urine. FDA also declines to change the image to be a depiction of a body part, in this case a bladder, as research shows that both youth and adults have a limited understanding of what a bladder looks like. For example, in one pilot study with 168 adolescents, only 7.7 percent could correctly label the bladder on a diagram (Ref. 152). This warning is intended to promote greater public understanding of bladder cancer caused by cigarette smoking. As stated in the preceding paragraph, bloody urine is a very common, and, in most cases, the first visible symptom of bladder cancer. The textual warning statement explains that smoking causes bladder cancer, which can lead to bloody urine. The accompanying, concordant, factually accurate image appropriately depicts bloody urine consistent with that seen in cases of bladder cancer caused by smoking. Because the required warning contains the textual warning statement and image paired together, the image aids in understanding the negative health consequence that is the focus of the textual warning statement, and vice versa.

Finally, we disagree with the assertion that the image is intended to evoke an emotional response. The image presents the health condition in a realistic and objective format, does not contain additional unnecessary details (*e.g.,* background setting), and does not contain any elements intended to evoke a negative emotional response.

5. ''WARNING: Smoking during pregnancy stunts fetal growth.''

This required warning consists of the textual warning statement ''WARNING: Smoking during pregnancy stunts fetal growth'' paired with a concordant, factually accurate, photorealistic image depicting a negative health consequence of smoking during pregnancy: An infant with low birth weight resulting from stunted fetal growth. The image shows a newborn infant on a medical scale, and the digital display on the scale reads four pounds.

In FDA's final consumer research study, this warning was reported to be new information by 40.0 percent of participants who viewed it. In the proposed rule, we explained that the two outcomes of ''new information'' and ''self-reported learning'' are predictive of whether new cigarette health warnings increase understanding of the risks associated with cigarette smoking. Compared to the average of the ratings for the four Surgeon General's warnings (the control condition in the study), this warning was statistically significantly ($p<0.05$, after adjusting for age group, smoking status, and multiple comparisons) higher on both providing new information and self-reported learning. In addition, this warning was statistically significantly higher than the Surgeon General's warnings on nearly all other outcomes measured. This warning grabbed attention more, resulted in more thinking about the risks, and was perceived to be more informative, to be more understandable, and to be more helpful in understanding the health effects of smoking. The warning was correctly recalled by 66.7 percent of participants, which was statistically significantly higher than the 25.7 percent who recalled the Surgeon General's warnings.

Most participants (83.9 percent) perceived the warning to be factual, a result that was not statistically different from the Surgeon General's warnings. Participants who viewed this warning showed statistically significant improvements in their health beliefs between Sessions 1 and 2, but not between Sessions 1 and 3, as compared to the changes in participants who viewed the Surgeon General's warnings. Full details of the results for this warning in FDA's final consumer research study are available in the study's final report (Ref. 17).

We received a number of comments on this warning, which we have summarized and responded to below.

(Comment 62) Some comments object to this proposed warning because they assert it is inaccurate and misleading. These comments question the accuracy of the visual depiction of the newborn infant, asserting that fetal growth and birth weight are not the same; the ''4.00 lbs.'' weight displayed in the image represents an extreme example of low birth weight due to smoking; the scale's depiction of ''4.00 lbs.'' conveys very low birth weight commonly associated with premature birth; and FDA has not demonstrated that a birth weight of four pounds is a likely outcome of maternal smoking.

Some comments suggest that the image of an infant on a scale that reads ''4.00 lbs.'' may be difficult to see and therefore recommend increasing the text size of the weight display to help consumers more easily and quickly identify the condition being depicted in the image.

Other comments raise concerns that the infant in the image appears unrealistic and that the low birth weight also relies on viewers/readers to understand what a healthy weight might be. One comment states that the image contains a non-essential element by including the infant's apparent ''distress,'' while another comment notes that ''it may not be apparent to all that four pounds is underweight, especially to those with a lower health literacy or to those who are first-time mothers.'' Other comments recommend changing the image to include an underweight infant next to an average-sized infant or to feature a small infant in an incubator attached to various tubes and lines to better communicate the increased risk of low birth weight.

One comment states the proposed warning ''seeks to advance FDA's anti-smoking message'' by evoking an emotional response in consumers because the image is ''designed to provoke an instinctive, emotional need in adult viewers to comfort the child.''

(Response 62) We disagree with comments suggesting that this warning is inaccurate or misleading. As explained at length in the proposed rule, FDA undertook a rigorous, multistep process to develop, test, and refine the textual warning statement, accompanying image, and the overall warning.

The textual warning statement ''WARNING: Smoking during pregnancy stunts fetal growth'' is factually accurate. As stated in the proposed rule, the 2004 Surgeon General's Report concluded that the evidence was sufficient to infer a causal relationship—the highest level of evidence of causal inferences based on the criteria applied in the Surgeon General's Reports—between maternal smoking and fetal growth restriction and preterm delivery (Ref. 138). The 2004 and a subsequent Surgeon General's Report summarized many studies that found a consistent and strong relationship between smoking and reduced birth weight as well as a strong dose-response relationship between smoking intensity and birth weight (Refs. 138 and 153). More recent studies further support the causal relationship between smoking and restricted fetal growth (Refs. 154–157). Further, a recent panel of 57 international leaders in the field of neonatal growth developed a consensus definition of fetal growth restriction using a Delphi method (Ref. 158), and both population-

based and customized percentiles for birth weight were accepted in the definition. As such, low birth weight is a strong and important indicator of fetal growth restriction.

Additionally, the image in the warning is factually accurate and depicts a common visual presentation of this negative health consequence. The visual depiction of stunted fetal growth as a newborn weighing four pounds on a scale clearly and accurately represents the negative health consequence of smoking focused in the textual warning statement, since, as described in the preceding paragraph, low birth weight is an important indicator of fetal growth restriction (Ref. 158). FDA disagrees with comments suggesting that four pounds is an ''extremely'' low birth weight. Epidemiological studies, which show that maternal cigarette smoking increases the risk for very low birth weight infants, define low birth weight as any weight less than 1,500 grams (which is equivalent to about 3 pounds, 4 ounces), therefore four pounds is not an ''extremely'' low birth weight (Refs. 159 and 160). Further, we disagree that the public will not understand that the infant is low birth weight because of the ''4.00 lbs.'' display on the scale or the infant's appearance. Throughout our iterative process of testing and refining this image, even when study participants did not know the definition of low birth weight, this image was understood as intended. Because the required warning contains the textual warning statement and image paired together, the image aids in understanding the negative health consequence that is the focus of the textual warning statement, and vice versa.

Further, the textual warning statement and image are concordant, and the warning is not ambiguous. The textual warning statement explains that smoking during pregnancy stunts fetal growth. The accompanying concordant and factually accurate image depicts a newborn infant with low birth weight due to stunted fetal growth resulting from maternal smoking. As previously stated, the goal of the required warnings is to promote greater public understanding of the negative health consequences of smoking by conveying factual information regarding the causal association between smoking and specific health conditions rather than conveying information about absolute or relative risk of these conditions. Similarly, the goal of this specific warning's image is not to convey that all babies born with stunted fetal growth weigh four pounds, but rather to depict a concordant, factually accurate, common visual presentation of the negative health consequence of smoking described by the textual warning statement.

We decline to make changes to the image to depict elements related to premature birth, such as placing the infant in an incubator or adding tubes. Stunted fetal growth does not necessarily result in premature birth, and premature birth is not the subject of this required warning. The image depicts a low birth weight infant, not necessarily a premature infant who would likely require (and thus be depicted with) additional interventions such as an incubator, oxygen, feeding tube, and additional monitoring (Ref. 161). This image depicts a factually accurate, common visual presentation of the health condition of stunted fetal growth and shows the condition as it is typically experienced.

We disagree with the assertion that the image is intended to evoke an emotional response. The image presents the health condition (stunted fetal growth) in a realistic and objective format, does not contain additional unnecessary details (*e.g.,* background setting), and does not contain any elements intended to evoke a negative emotional response. The inclusion of the weight on the scale further explains that the infant has a low birth weight. We also disagree that the infant in the image is in apparent ''distress.'' Crying among newborns is common and expected in this setting. It is an indicator of healthy lung function so much so that it is included in the widely used APGAR scoring used one and five minutes after birth (Ref. 162).

Finally, with regard to comments suggesting that the image's ''4.00 lbs.'' weight display on the scale may be difficult to see, we agree that this important element of the image may be difficult to view in certain sizes of cigarette packages or advertisements. As a result, for this required warning, we have increased the contrast and size of the weight display in the image to improve image clarity.

6. ''WARNING: Smoking can cause heart disease and strokes by clogging arteries.''

This required warning consists of the textual warning statement ''WARNING: Smoking can cause heart disease and strokes by clogging arteries'' paired with a concordant, factually accurate, photorealistic image depicting a patient who recently underwent heart surgery to treat heart disease caused by smoking. The image shows the chest of a man (aged 60–70 years) wearing an open hospital gown. The man has a large, recently-sutured incision running down the middle of his chest and is undergoing post-operative monitoring.

In FDA's final consumer research study, this warning was reported to be new information by 52.1 percent of participants who viewed it. In the proposed rule, we explained that the two outcomes of ''new information'' and ''self-reported learning'' are predictive of whether new cigarette health warnings increase understanding of the risks associated with cigarette smoking. Compared to the average of the ratings for the four Surgeon General's warnings (the control condition in the study), this warning was statistically significantly ($p<0.05$, after adjusting for age group, smoking status, and multiple comparisons) higher on both providing new information and self-reported learning. In addition, this warning was statistically significantly higher than the Surgeon General's warnings on nearly all other outcomes measured. This warning grabbed attention more, resulted in more thinking about the risks, and was perceived to be more informative, to be more understandable, and to be more helpful in understanding the health effects of smoking. The warning was correctly recalled by 49.4 percent of participants, which was statistically significantly higher than the 25.7 percent who recalled the Surgeon General's warnings.

Most participants (85.2 percent) perceived the warning to be factual, a result that was not statistically different from the Surgeon General's warnings. Participants who viewed this warning showed statistically significant improvements in their health beliefs between Sessions 1 and 2, but not between Sessions 1 and 3 as compared to the changes in participants who viewed the Surgeon General's warnings. Full details of the results for this warning in FDA's final consumer research study are available in the study's final report (Ref. 17).

We received a number of comments on this warning, which we have summarized and responded to below.

(Comment 63) Some comments object to this proposed warning because they assert it is inaccurate and misleading. One comment suggests that the warning is misleading because it depicts a man who has had recent open-heart surgery, presumably coronary artery bypass grafting (CABG), and the comment provides data showing that in-patient percutaneous coronary interventions (PCIs) are 2.5 times more common than open-heart CABG surgery for treating coronary artery disease (Ref. 163). Another comment asserts that the image depicts a ''worst case, rather than

representative scenario.'' One comment states that the textual warning statement and image are not concordant because the text indicates that smoking can lead to heart disease and strokes, but the image, on its own, does not convey that the individual depicted either suffered from heart disease or a stroke. Another comment asserts that the warning ''seeks to advance FDA's anti-smoking message'' by evoking an emotional response in consumers because the depiction of a man with a large, recently-sutured incision ''is intended to disgust or shock consumers'' or ''to make consumers fearful of the prospect of needing to undergo major heart surgery and medical monitoring.''

Other comments support the inclusion of this warning in the final rule, emphasizing the strong causal link, based on the conclusions drawn from past Surgeon General's Reports, between cigarette smoking and heart disease and stroke. The comments also reference a 2018 meta-analysis of 141 cohort studies that found that smoking approximately one cigarette per day carries a much higher risk for developing coronary heart disease and stroke than would be expected if the risk increased in a linear dose-response relationship (Ref. 164).

(Response 63) We disagree with comments suggesting that this warning is inaccurate or misleading. FDA undertook a rigorous, multistep process to develop, test, and refine the textual warning statement, accompanying image, and the overall warning.

The textual warning statement ''WARNING: Smoking can cause heart disease and strokes by clogging arteries'' is factually accurate. As described in the proposed rule (see section VII.A.6 of the proposed rule), coronary heart disease—often simply called heart disease—is a disorder of the blood vessels of the heart that can lead to a heart attack. Stroke occurs when blood supply to part of the brain is interrupted or reduced, depriving brain tissue of oxygen and nutrients (Ref. 165). Atherosclerosis, or clogged arteries, is a disease in which plaque builds up inside the arteries that carry oxygen-rich blood to the heart and other parts of the body and can lead to heart attack and stroke through thrombosis, or blockage of the arteries (Refs. 3 and 165). Most coronary heart disease involves atherosclerosis, or clogged arteries. Also as described in the proposed rule, Surgeon General's Reports since the 1970s have concluded that smoking is causally related to heart disease and stroke (Refs. 138 and 166), and smoking is consistently identified as a major risk factor for heart disease and stroke (Refs. 35, 115, 116, and 167). Across many studies over time, a clear dose-response relationship has been established with smoking more cigarettes and smoking for a longer time linked to greater risk of heart disease and stroke. More recent evidence demonstrates that even a very low frequency of smoking (*i.e.,* even as few as one cigarette per day) has a measurable increase in the risk for cardiovascular disease (CVD) (Ref. 164).

Additionally, the image in the warning is factually accurate and depicts a common visual presentation of this negative health consequence. The image shows the chest of a man (aged 60–70 years) wearing an open hospital gown. The man has a large, recently-sutured incision running down the middle of his chest and is undergoing post-operative monitoring. As one comment notes, while inpatient discharges for CABG surgery have decreased over time, in 2014 there were still over 350,000 individuals who underwent the procedure as a consequence of coronary artery disease (Ref. 163). The appropriate use criteria and decision for treatment approaches is based on many clinical factors, with both CABG (as depicted) and PCI commonly used (Ref. 168). Therefore, this image depicts a factually accurate, common visual presentation of the health condition and shows the disease state as it is typically experienced.

Further, the textual warning statement and image are concordant, and the warning is not ambiguous. The textual warning statement explains that smoking can cause heart disease and strokes by clogging arteries. The accompanying concordant and factually accurate image depicts a patient who received treatment for heart disease caused by clogged arteries due to smoking. Because the required warning contains the textual warning statement and image paired together, the image aids in understanding the negative health consequence that is the focus of the textual warning statement, and vice versa.

Finally, we disagree with the assertion that the image is intended to evoke an emotional response. The image presents the health condition in a realistic and objective format, does not contain additional unnecessary details (*e.g.,* background setting), and does not contain any elements intended to evoke a negative emotional response.

7. ''WARNING: Smoking causes COPD, a lung disease that can be fatal.'' [image of man with oxygen tank]

This required warning consists of the textual warning statement ''WARNING: Smoking causes COPD, a lung disease that can be fatal'' paired with a concordant, factually accurate, photorealistic image depicting a man receiving oxygen support because he has COPD caused by cigarette smoking. The image shows the head and neck of a man (aged 50–60 years) who has a nasal canula under his nose supplying oxygen; the oxygen tank can be seen behind his left shoulder.

In FDA's final consumer research study, this warning was reported to be new information by 35.7 percent of participants who viewed it. In the proposed rule, we explained that the two outcomes of ''new information'' and ''self-reported learning'' are predictive of whether new cigarette health warnings increase understanding of the risks associated with cigarette smoking. Compared to the average of the ratings for the four Surgeon General's warnings (the control condition in the study), this warning was statistically significantly ($p<0.05$, after adjusting for age group, smoking status, and multiple comparisons) higher on both providing new information and self-reported learning. In addition, this warning was statistically significantly higher than the Surgeon General's warnings on nearly all other outcomes measured. This warning grabbed attention more, resulted in more thinking about the risks, and was perceived to be more informative, to be more understandable, and to be more helpful in understanding the health effects of smoking. The warning was correctly recalled by 57.8 percent of participants, which was statistically significantly higher than the 25.7 percent who recalled the Surgeon General's warnings.

Most participants (83.8 percent) perceived the warning to be factual, a result that was not statistically different from the Surgeon General's warnings. Despite the strong results on nearly all other measures included in the study, this warning did not show statistically significant improvements in health beliefs between either Sessions 1 and 2 or between Sessions 1 and 3 over the changes in participants who viewed the Surgeon General's warnings, which is not surprising given the relatively brief exposure to the warning. Full details of the results for this warning are available in FDA's final consumer research study are available in the study's final report (Ref. 17).

We received a number of comments on this warning, which we have summarized and responded to below.

(Comment 64) Multiple comments provide data supporting this warning, since smoking is the leading cause of COPD. One comment emphasizes that a warning depicting COPD—either with an image of a diseased lung or the need

for oxygen as a result of COPD—would be ''more impactful than a simple statement that 'nicotine is addictive' or 'smoking is dangerous to your health.' '' The same comment notes that COPD is the fourth leading cause of death, is one of the costliest conditions with respect to hospital readmissions, and the medical profession witnesses ''the devastating consequences of tobacco use among COPD patients every day.''

(Response 64) We agree that this cigarette health warning is important, focuses on a serious health risk of smoking, and will promote greater public understanding of the negative health consequences of smoking.

(Comment 65) Some comments object to this warning because they assert it is inaccurate and misleading in a number of respects. One comment states that the image does not, on its own, convey purely factual information because ''[n]o reasonable consumer would be able to determine from the image alone that the man depicted suffers from COPD.'' Rather, the comment suggests, all the image conveys is that the man needs oxygen support. Another comment confirms that long-term oxygen therapy, delivered through a nasal canula, as depicted in the proposed warning, is one of several treatments for COPD (Ref. 169); however, the comment asserts that the proposed warning depicts a ''worst case scenario'' without discussion of the proportion of smokers developing COPD who will require long-term oxygen therapy or home oxygen. Finally, one comment states that the proposed warning ''seeks to advance FDA's anti-smoking message'' by evoking an emotional response in consumers, because the image ''appears designed to make consumers fearful of the prospect of needing to rely upon an oxygen tank to survive.''

(Response 65) We disagree with comments suggesting that this warning is inaccurate or misleading. As explained at length in the proposed rule, FDA undertook a rigorous, multistep process to develop, test, and refine the textual warning statement, accompanying image, and the overall warning.

The textual warning statement ''WARNING: Smoking causes COPD, a lung disease that can be fatal'' is factually accurate. As stated in the proposed rule, COPD includes the diseases emphysema and chronic bronchitis. The 1964 Surgeon General's Report concluded that smoking is a primary cause of chronic bronchitis, and subsequent reports summarized additional evidence to conclude, in the 2004 Surgeon General's Report—at the highest level of evidence of causal inferences from the criteria applied in the Surgeon General's Reports—that the evidence is sufficient to infer a causal relationship between active smoking and COPD morbidity and mortality (Refs. 138, 170, and 171). The 2014 Surgeon General's Report reinforced and extended this evidence to discuss the relationship between smoking and COPD mortality (Ref. 3). The 2014 Surgeon General's Report concluded that the evidence is sufficient to infer—once again, the highest level of evidence of causal inferences from the criteria applied in the Surgeon General's Reports—that smoking is in fact the dominant cause of COPD in the United States (Ref. 3). The mortality risk from COPD for current smokers compared to never smokers was 25.61 times higher for men and 22.35 times higher for women, according to 50-year trends published in the *New England Journal of Medicine* (Ref. 172). There are about 128,000 COPD deaths in the United States each year, of which 101,000 (79 percent) are attributable to smoking (Ref. 3).

Additionally, the image in the warning is factually accurate and depicts a common visual presentation of this negative health consequence. Oxygen therapy is not rare and is recommended for symptom relief and prolonging life, and many patients with COPD can use oxygen for several years. Oxygen therapy may be used with patients with COPD who have symptoms of both severe and moderate hypoxemia (*i.e.,* abnormally low level of oxygen in the blood) to improve survival and quality of life (Refs. 173 and 174). Each year, more than 1.5 million adults in the United States use supplemental oxygen therapy (Ref. 175), including those with COPD. For example, among Medicare beneficiaries with COPD in 2010, 40.5 percent received oxygen therapy and 18.5 percent received sustained oxygen therapy (Ref. 176). Quality of life can be improved for adults with COPD through the regular use of long-term oxygen therapy (Ref. 177). Therefore, this image depicts a factually accurate, common visual presentation of the health condition and shows the disease state and treatment for the disease as it is typically experienced.

Further, the textual warning statement and image are concordant, and the warning is not ambiguous. The textual warning statement explains that smoking causes COPD, a fatal lung disease. Including the qualifying clause stating that COPD is a fatal lung disease further explains and provides important information of this negative health consequence of smoking. The accompanying concordant and factually accurate image depicts a man with COPD receiving oxygen treatment. Because the required warning contains the textual warning statement and image paired together, the image aids in understanding the negative health consequence that is the focus of the textual warning statement, and vice versa.

Finally, we disagree with the assertion that the image is intended to evoke an emotional response. The image presents the health condition in a realistic and objective format, does not contain additional unnecessary details (*e.g.,* background setting), and does not contain any elements intended to evoke a negative emotional response.

(Comment 66) One comment asserts that FDA has not provided any scientific basis for requiring two cigarette health warnings on COPD (identical textual warning statements paired with two different images) when only one warning was proposed for all other health conditions.

(Response 66) As noted in the proposed rule (see section VI.B of the proposed rule), based on the results of FDA's first consumer research study (Ref. 12), FDA selected a total of 15 textual warning statements for testing in the final consumer research study (Ref. 17). However, when each of the textual warning statements were paired with concordant photorealistic images, two of the textual warning statements (''WARNING: Tobacco smoke causes fatal lung disease in nonsmokers'' and ''WARNING: Smoking causes COPD, a lung disease that can be fatal'') shared similar concordant images (''diseased lungs''). To preserve the option of potentially requiring both textual warning statements but without using two similar images, FDA paired an additional concordant image (''man with oxygen tank'') with the COPD textual warning statement for further testing. Therefore, FDA tested a total of 16 text-and-image pairings in the final quantitative consumer research study. Results from that study show that both images (''diseased lungs'' and ''man with oxygen tank''), paired with the same COPD textual warning statement, performed well across the outcomes measured, indicating that either pairing would advance the Government's interest in promoting greater public understanding of the negative health consequences of cigarette smoking (Ref. 17). We are therefore finalizing this cigarette health warning—and not the COPD warning with the image of diseased lungs—to avoid having two identical textual warning statements about COPD and to avoid having two

similar, concordant images of diseased lungs paired with different textual warning statements.

8. ''WARNING: Smoking reduces blood flow, which can cause erectile dysfunction.''

This required warning consists of the textual warning statement ''WARNING: Smoking reduces blood flow, which can cause erectile dysfunction'' paired with a concordant, factually accurate, photorealistic image depicting a man who is experiencing erectile dysfunction caused by smoking. The image shows a man (aged 50–60 years) sitting on the edge of a bed and leaning forward, with one elbow resting on each knee. The man's head is tilted down, with his forehead pressed into the knuckles of his right hand. Behind him on the bed, his female partner looks off in another direction.

In FDA's final consumer research study, this warning was reported to be new information by 78.8 percent of participants who viewed it. In the proposed rule, we explained that the two outcomes of ''new information'' and ''self-reported learning'' are predictive of whether new cigarette health warnings increase understanding of the risks associated with cigarette smoking. Compared to the average of the ratings for the four Surgeon General's warnings (the control condition in the study), this warning was statistically significantly ($p<0.05$, after adjusting for age group, smoking status, and multiple comparisons) higher on both providing new information and self-reported learning. In addition, this warning was statistically significantly higher than the Surgeon General's warnings on nearly all other outcomes measured. This warning grabbed attention more, resulted in more thinking about the risks, and was perceived to be more informative, to be more understandable, and to be more helpful in understanding the health effects of smoking. The warning was correctly recalled by 61.4 percent of participants, which was statistically significantly higher than the 25.7 percent who recalled the Surgeon General's warnings.

Most participants (72.4 percent) perceived the warning to be factual, a result that was statistically significantly lower than the control condition. Participants who viewed this warning showed statistically significant improvements in their health beliefs between Sessions 1 and 2, but not between Sessions 1 and 3, as compared to the changes in participants who viewed the Surgeon General's warnings. Full details of the results for this warning in FDA's final consumer research study are available in the study's final report (Ref. 17).

We received a number of comments on this warning, which we have summarized and responded to below.

(Comment 67) Some comments object to this warning because they assert it is inaccurate and misleading in a number of respects. One comment asserts that the image, on its own, does not convey purely factual information, because ''it does not provide *any* health information'' (emphasis added) and ''in no way illuminates how smoking could cause erectile dysfunction.'' The comment further states that the warning is misleading because it emphasizes a chronic, non-fatal condition rather than other conditions with high mortality rates. The comment also states that the warning ''focuses on erectile dysfunction while omitting mention of more common side effects of low blood flow, such as numbness or weakness in the legs.'' Finally, the comment states that the proposed warning ''seeks to advance FDA's anti-smoking message'' by evoking an emotional response in consumers, because the image ''is clearly designed to generate embarrassment and shame in viewers regarding the sensitive topic of sexual intimacy.''

Another comment acknowledges that some health conditions are more difficult to depict than others. In the case of this warning, the comment explains that, while ''literal depictions'' of the health conditions are generally preferable, the use of a more ''symbolic'' image is ''justified'' for this health condition and warning.

(Response 67) We disagree with comments suggesting that this warning is inaccurate or misleading. As explained at length in the proposed rule, FDA undertook a rigorous, multistep process to develop, test, and refine the textual warning statement, accompanying image, and the overall warning.

The textual warning statement ''WARNING: Smoking reduces blood flow, which can cause erectile dysfunction'' is factually accurate. As discussed in the proposed rule and in reports of the Surgeon General, there is strong support that smoking causes erectile dysfunction. The 2014 Surgeon General's Report concluded that the evidence is sufficient to infer a causal relationship—the highest level of evidence of causal inferences from the criteria applied in the Surgeon General's Reports—between smoking and erectile dysfunction (Ref. 3). A recent meta-analysis of studies that included 50,360 participants found that smoking more cigarettes and smoking for a longer time were associated with increased erectile dysfunction risk (Ref. 178). Smokers have been found to have a 40 percent increased risk of erectile dysfunction in studies such as the Health Professionals Follow-up Study and the Olmsted County Study of Urinary Symptoms and Health Status (Refs. 179 and 180). Erectile dysfunction is likely under-reported in epidemiological studies; therefore, the effect estimates observed in studies are likely an underestimate. Finally, FDA disagrees with the comment suggesting only conditions with high mortality rates will directly advance the Government's interest. The substantial public health burden of cigarette smoking includes individuals with chronic, non-fatal diseases, and the Government has a substantial interest in improving public understanding about the negative health consequences of smoking that encompass health conditions beyond those with the highest mortality rates.

Additionally, the image in the warning is factually accurate and depicts a common visual presentation of this negative health consequence. The man in the image is aged 50–60 years, which is an appropriate age range for men experiencing erectile dysfunction caused by cigarette smoking (Ref. 181). Also, as one comment notes, some health conditions are more difficult to depict literally and therefore depicting the ''situational context'' is justified. In the case of this required warning, FDA included additional realistic and contextual details (*e.g.,* the man's posture, state of undress, bedroom setting, intimate partner) to depict the health condition.

Further, the textual warning statement and image are concordant, and the warning is not ambiguous. This warning is intended to promote greater public understanding that cigarette smoking reduces blood flow and can cause erectile dysfunction. The textual statement explains that smoking reduces blood flow, which can cause erectile dysfunction, thereby describing the mechanism through which smoking can cause this health effect. The accompanying concordant and factually accurate image depicts a man experiencing erectile dysfunction caused by smoking. Because the required warning contains the textual warning statement and image paired together, the image aids in understanding the negative health consequence that is the focus of the textual warning statement, and vice versa.

Finally, we disagree with the assertion that the image is intended to evoke an emotional response. The image

presents the health condition in a realistic and appropriately contextual format, does not contain additional unnecessary details (*e.g.,* background setting), and does not contain any elements intended to evoke a negative emotional response.

9. ''WARNING: Smoking reduces blood flow to the limbs, which can require amputation.''

This required warning consists of the textual warning statement ''WARNING: Smoking reduces blood flow to the limbs, which can require amputation'' paired with a concordant, factually accurate, photorealistic image depicting the feet of a person who had several toes amputated due to tissue damage resulting from peripheral vascular disease (PVD) caused by cigarette smoking.

In FDA's final consumer research study, this warning was reported to be new information by 74.7 percent of participants who viewed it. In the proposed rule, we explained that the two outcomes of ''new information'' and ''self-reported learning'' are predictive of whether new cigarette health warnings increase understanding of the risks associated with cigarette smoking. Compared to the average of the ratings for the four Surgeon General's warnings (the control condition in the study), this warning was statistically significantly ($p<0.05$, after adjusting for age group, smoking status, and multiple comparisons) higher on both providing new information and self-reported learning. In addition, this warning was statistically significantly higher than the Surgeon General's warnings on nearly all other outcomes measured. This warning grabbed attention more, resulted in more thinking about the risks, and was perceived to be more informative, to be more understandable, and to be more helpful in understanding the health effects of smoking. The warning was correctly recalled by 73.8 percent of participants, which was statistically significantly higher than the 25.7 percent who recalled the Surgeon General's warnings.

Most participants (76.7 percent) perceived the warning to be factual, a result that was significantly lower than the control condition. Participants who viewed this warning showed statistically significant improvements in their health beliefs between both Sessions 1 and 2 and Sessions 1 and 3 as compared to the changes in participants who viewed the Surgeon General's warnings. Full details of the results for this warning are available in FDA's final consumer research study are available in the study's final report (Ref. 17).

We received a number of comments on this warning, which we have summarized and responded to below.

(Comment 68) Some comments object to this proposed warning because they assert it is inaccurate and misleading in a number of respects. One comment states that the warning's image does not convey purely factual information because ''[n]o reasonable consumer would be able to determine from the image alone'' that the individual's amputated toes were due to tissue damage from PVD. The comment asserts that ''the text gives meaning to a disturbing image, rather than the other way around.'' Two comments question the accuracy of the image, asserting that it depicts Buerger's disease, ''a condition that could affect, at most, one in 1,000 smokers.'' One comment suggests the proposed warning is misleading, because ''only a small proportion of patients'' with PVD require amputation, and the prevalence of PVD in patients who have no symptoms is high.

Another comment states that the text and image are not concordant because ''[n]othing about the picture indicates that the amputation resulted from reduced blood flow, let alone that the reduced blood flow reflects peripheral vascular disease.'' Instead, the comment claims, the ''mismatch'' between the text and the image ''adds to the fear and confusion a consumer would experience when viewing the warning.'' Finally, the comment states that the proposed warning ''seeks to advance FDA's anti-smoking message'' by evoking an emotional response in consumers, because the image ''is disturbing and unsightly and is clearly designed to provoke either disgust at the sight of the image, fear at the prospect of undergoing an amputation, or both.''

(Response 68) We disagree with comments suggesting that this warning is inaccurate or misleading. As explained at length in the proposed rule, FDA undertook a rigorous, multistep process to develop, test, and refine the textual warning statement, accompanying image, and the overall warning.

The textual warning statement ''WARNING: Smoking reduces blood flow to the limbs, which can require amputation'' is factually accurate. As discussed in the proposed rule, smoking is known to affect cardiovascular health in a number of ways. Smoking can cause peripheral arterial disease (PAD), also known as PVD, a health condition that causes arteries to narrow, which limits the flow of oxygen-rich blood to organs and other parts of the body, including arteries in the legs (Ref. 182). Complications of reduced blood flow to the limbs include amputation or loss of limbs due to tissue damage caused by poor oxygen supply. Numerous Surgeon General's Reports have summarized the strong causal evidence between smoking and PAD/PVD and concluded that cigarette smoking is the most powerful risk factor predisposing individuals to this condition (Refs. 3 and 183). Moreover, also as discussed in the proposed rule (see section VII.A.10 of the proposed rule), the population health burden of PAD/PVD is high: overall prevalence of PAD/PVD was found to be 13.5 percent in 2012 in the Atherosclerosis Risk in Communities study (Ref. 184); a meta-analysis found that the risk of the condition was 2.71 times greater for current smokers and 1.67 times greater for former smokers compared to never smokers (Ref. 185); and the 2014 Surgeon General's Report showed that risk estimates have increased over time (Ref. 3).

Additionally, the image in the warning is factually accurate and depicts a common visual presentation of this negative health consequence. The image shows a complication resulting from this health condition, namely, toes that have been amputated due to tissue damage caused by reduced blood flow due to PAD/PVD. As discussed in the proposed rule, among people with critical limb ischemia (*i.e.,* a severe blockage of the arteries that greatly reduces blood flow due to PAD/PVD), 25 percent have amputations each year (Ref. 186). Another article estimates that ''over 90% of all limb amputations in the Western world occur as a direct or indirect consequence'' of PAD/PVD (Ref. 187). Because the warning's image depicts a person who had several toes amputated due to tissue damage resulting from PAD/PVD caused by cigarette smoking of undefined etiology, the image is consistent with PAD/PVD and is not is specific to Buerger's disease, as one comment suggested (see Refs. 188 and 189). Therefore, this image depicts a factually accurate, common visual presentation of the outcome of the health condition and shows the disease state as it may be experienced.

Further, the textual warning statement and image are concordant, and the warning is not ambiguous. The textual warning statement explains that smoking reduces blood flow to the limbs, which can require amputation. The accompanying concordant and factually accurate image depicts the feet of a person who has had several toes amputated due to tissue damage

resulting from reduced blood flow to the limbs caused by cigarette smoking. Because the required warning contains the textual warning statement and image paired together, the image aids in understanding the negative health consequence that is the focus of the textual warning statement, and vice versa.

Finally, we disagree with the assertion that the image is intended to evoke an emotional response. The image presents the health condition in a realistic and objective format, does not contain additional unnecessary details (*e.g.,* background setting, surgical instruments used to remove the toes), and does not contain any elements intended to evoke a negative emotional response.

10. ''WARNING: Smoking causes type 2 diabetes, which raises blood sugar.''

This required warning consists of the textual warning statement ''WARNING: Smoking causes type 2 diabetes, which raises blood sugar'' paired with a concordant, factually accurate, photorealistic image depicting a personal glucometer device being used to measure the blood glucose level of a person with type 2 diabetes caused by cigarette smoking. The digital display reading of 175 mg/dL and a notation on the glucometer indicate a high blood sugar level.

In FDA's final consumer research study, this warning was reported to be new information by 87.2 percent of participants who viewed it. In the proposed rule, we explained that the two outcomes of ''new information'' and ''self-reported learning'' are predictive of whether new cigarette health warnings increase understanding of the risks associated with cigarette smoking. Compared to the average of the ratings for the four Surgeon General's warnings (the control condition in the study), this warning was statistically significantly ($p<0.05$, after adjusting for age group, smoking status, and multiple comparisons) higher on both providing new information and self-reported learning. In addition, this warning was statistically significantly higher than the Surgeon General's warnings on nearly all other outcomes measured. This warning grabbed attention more, resulted in more thinking about the risks, and was perceived to be more informative, to be more understandable, and to be more helpful in understanding the health effects of smoking. The warning was correctly recalled by 62.3 percent of participants, which was statistically significantly higher than the 25.7 percent who recalled the Surgeon General's warnings.

Most participants (64.0 percent) perceived the warning to be factual, a result that was statistically significantly lower than the control condition (see section VI for a fuller discussion of the ''perceived factualness'' outcome). Participants who viewed this warning showed statistically significant improvements in their health beliefs between both Sessions 1 and 2 and Sessions 1 and 3 as compared to the changes in participants who viewed the Surgeon General's warnings. Full details of the results for this warning in FDA's final consumer research study are available in the study's final report (Ref. 17).

We received a number of comments on this warning, which we have summarized and responded to below.

(Comment 69) Multiple comments support the inclusion of this warning in the final rule and provide additional epidemiological and other scientific data to support the text and image components, including a scientific review that concluded that cigarette smoking increases the risk for type 2 diabetes incidence (Ref. 190).

(Response 69) FDA appreciates the submission of additional scientific and other support for the inclusion of this warning focused on smoking causing type 2 diabetes. We agree that this cigarette health warning is important, focuses on a serious health risk of smoking, and will promote greater public understanding of the negative health consequences of smoking.

(Comment 70) Some comments recommend FDA consider modifying the textual warning statement language or adding a separate warning related to smoking's causal link to type 2 diabetes. For example, suggestions from comments include ''Smoking causes type 2 diabetes, which can cause kidney disease or failure'' and ''Smokers with diabetes (and people with diabetes exposed to secondhand smoke) have a heightened risk of CVD, premature death, microvascular complications, and worse glycemic control when compared with nonsmokers.'' Some comments recommend that the textual warning statement convey the ''gravity'' of the disease or the serious complications of potentially greater concern to consumers without diagnosed diabetes (*e.g.,* CVD, kidney disease, blindness, blurry vision, numbness in the hands and feet, amputation).

(Response 70) While FDA agrees that there are other serious complications resulting from type 2 diabetes, we decline to make the suggested changes. The textual warning statement is factually accurate and is supported by strong epidemiological evidence that confirms the appropriate use of the causal language as written. The phrasing is appropriate, accurate, and consistent with the other required warnings, and it has performed well in FDA's consumer research studies, both on its own (in the first consumer research study) and when paired with a concordant photorealistic image (in the final consumer research study). The results of our rigorous science-based, iterative research process indicate that this warning will advance the Government's interest in promoting greater public understanding of the negative health consequences of smoking.

(Comment 71) One comment recommends FDA remove numeric digital display readings from the glucometer portion of the image because ''desired blood glucose targets vary among individuals with diabetes'' and including a specific numeric value in the image ''could be confusing for people with diabetes.'' The comment raises concern that individuals could misconstrue such a value (*i.e.,* 175) as indicative of the appropriate glycemic target for their own care. Another comment suggests blood sugar levels may be less meaningful to some people.

(Response 71) FDA declines to make the suggested change. As the comment notes, there may be a range of desired blood glucose targets for different individuals; however, type 2 diabetes is defined as a fasting blood sugar greater than 126 mg/dL (Ref. 191), which is clearly and accurately depicted in this image. Further, the required warnings are not intended to provide individual diagnostic medical information or encourage individuals to seek treatment, but rather to promote greater public understanding of the negative health consequences of cigarette smoking—in this case, that smoking causes type 2 diabetes, which raises blood sugar.

(Comment 72) A comment from a group of research scientists shares findings from a recent study of 443 U.S. adults testing images for a sugar-sweetened beverage warning about type 2 diabetes. The comment states that an image similar to the one proposed here was the most common choice (selected by 34 percent of participants) of an image that ''best represented'' type 2 diabetes.

(Response 72) FDA appreciates the submission of this study; however, the study does not appear to be published and few details were submitted about the study methods or full results.

(Comment 73) Some comments object to this proposed warning, because they assert it is inaccurate and misleading in a number of respects. One comment states that the image, on its own, does

not convey purely factual information, because ''the average consumer is unlikely to be aware of the meaning of the '175' reading on the glucometer (or even to recognize the device as a glucometer).'' For that reason, the comment states that the text and image are not concordant because the image ''does not relate to diabetes without knowledge of additional information not depicted.'' Another comment suggests that the image is not accurate because a blood sugar level of 175 mg/dL is ''well in excess of the minimal threshold for diabetes.''

One comment states that the proposed warning ''seeks to advance FDA's anti-smoking message'' by evoking an emotional response in consumers, because the image ''appears designed to provoke the emotional reaction of fear or disgust that many experience when faced with the prospect of a medical procedure involving needles and drawing blood.'' Moreover, the comment claims that the depiction of blood being drawn ''threatens to cause an emotional or fearful reaction in many consumers'' and ''is not necessary'' to inform consumers regarding the risk of type 2 diabetes.

(Response 73) We disagree with comments suggesting that this warning is inaccurate or misleading. As explained at length in the proposed rule, FDA undertook a rigorous, multistep process to develop, test, and refine the textual warning statement, accompanying image, and the overall warning.

The textual warning statement ''WARNING: Smoking causes type 2 diabetes, which raises blood sugar'' is factually accurate. This statement is supported by strong epidemiological evidence that confirms the appropriate use of the causal language as written, as other comments note. The phrasing is also appropriate, accurate, and consistent with the other required warnings. The 2014 Surgeon General's Report concluded that: (1) The evidence is sufficient to infer—the highest level of evidence of causal inferences from the criteria applied in the Surgeon General's Reports—that cigarette smoking is a cause of type 2 diabetes; (2) the risk of developing diabetes is 30 to 40 percent higher for active smokers than nonsmokers; and (3) there is a relationship between increased number of cigarettes smoked and increased risk of developing diabetes (Ref. 3). Across the 25 studies included in the 2014 Surgeon General's Report's updated summary, the associations were strong and consistent and were found in many subgroups, and these results have been replicated in many different study populations and study locations. Moreover, additional scientific support for this causal link was submitted in other comments (see, *e.g.,* Ref. 190).

Additionally, the image in the warning is factually accurate and depicts a common visual presentation of this negative health consequence. The image depicts a common action taken by people with type 2 diabetes: Glucose monitoring. According to the American Diabetes Association, ''[f]or many people with diabetes, glucose monitoring is key for the achievement of glycemic targets'' and is ''an integral component of effective therapy of patients taking insulin'' (Refs. 192 and 193). Frequent testing of blood glucose is a reality for people with diabetes, and the image of a personal glucometer device being used to measure the blood glucose level is a common depiction of diabetes. Thus, there is support that an image of routine glucose monitoring is representative of type 2 diabetes in other contexts.

With regard to the numerical display, we disagree that the image depicting a blood sugar level of 175 mg/dL is inaccurate. While diabetes is defined as a fasting blood sugar greater than 126 mg/dL, there are more complex criteria needed for an accurate diagnosis of type 2 diabetes (Ref. 194). A glucose level of 175 mg/dL is consistent with the American Diabetes Association guidelines, which recommend patients target peak post-meal blood glucose levels of <180 mg/dL to help lower average glycemic levels and improve glycemic control (Ref. 192). Therefore, this image depicts a factually accurate, common visual presentation of the health condition and shows the disease state as it is typically experienced.

Further, the textual warning statement and image are concordant, and the warning is not ambiguous. The textual warning statement explains that smoking can cause type 2 diabetes, which raises blood sugar. The accompanying concordant and factually accurate image depicts a personal glucometer device being used to measure the blood glucose level of a person with type 2 diabetes caused by cigarette smoking. Because the required warning contains the textual warning statement and image paired together, the image aids in understanding the negative health consequence that is the focus of the textual warning statement, and vice versa.

Finally, we disagree with the assertion that the image is intended to evoke an emotional response. The image presents the health condition in a realistic and objective format, does not contain additional unnecessary details (*e.g.,* background setting), and does not contain any elements intended to evoke a negative emotional response.

11. ''WARNING: Smoking causes cataracts, which can lead to blindness.''

This required warning consists of the textual warning statement ''WARNING: Smoking causes cataracts, which can lead to blindness'' paired with a concordant, factually accurate, photorealistic image depicting a closeup of the face of a man (aged 65 years or older) who has a cataract caused by cigarette smoking. The man's right pupil is covered by a large cataract.

In FDA's final consumer research study, this warning was reported to be new information by 88.7 percent of participants who viewed it. In the proposed rule, we explained that the two outcomes of ''new information'' and ''self-reported learning'' are predictive of whether new cigarette health warnings increase understanding of the risks associated with cigarette smoking. Compared to the average of the ratings for the four Surgeon General's warnings (the control condition in the study), this warning was statistically significantly ($p<0.05$, after adjusting for age group, smoking status, and multiple comparisons) higher on both providing new information and self-reported learning. In addition, this warning was statistically significantly higher than the Surgeon General's warnings on nearly all other outcomes measured. This warning grabbed attention more, resulted in more thinking about the risks, and was perceived to be more informative, to be more understandable, and to be more helpful in understanding the health effects of smoking. The warning was correctly recalled by 53.0 percent of participants, which was statistically significantly higher than the 25.7 percent who recalled the Surgeon General's warnings.

Most participants (65.5 percent) perceived the warning to be factual, a result that was statistically significantly lower than the control condition (see section VI for a fuller discussion of the ''perceived factualness'' outcome). Participants who viewed this warning showed statistically significant improvements in their health beliefs between both Sessions 1 and 2 and Sessions 1 and 3 as compared to the changes in participants who viewed the Surgeon General's warnings. Full details of the results for this warning in FDA's final consumer research study are available in the study's final report (Ref. 17).

We received a number of comments on this warning, which we have summarized and responded to below.

(Comment 74) Multiple comments strongly support the inclusion of this proposed warning in the final rule and provide additional epidemiological and other scientific data to support the text and image components of this warning.

(Response 74) FDA agrees with the comments that this cigarette health warning is important, focuses on a serious health risk of smoking, and will promote greater public understanding of the negative health consequences of smoking.

(Comment 75) Some comments recommend that, since women generally have a longer life expectancy than men in the United States and are therefore more likely to develop age-related eye problems, FDA should consider changing the image to one of a woman with a cataract.

(Response 75) We decline to make this revision. The warning is factually accurate and appropriate for the purpose of this rule, which is to promote greater public understanding of the negative health consequences of cigarette smoking. It is not feasible, nor is it our intention, for a single warning to convey all the information that may be related to a particular health condition, such as populations with the highest prevalence of a disease, projected incidence rates, relative risk, mortality rates, or disparities in affected populations. Rather, this required warning presents a factually accurate visual depiction of the negative health condition that is concordant with the paired textual warning statement.

(Comment 76) Some comments object to this warning because they assert it is inaccurate and misleading in a number of respects. One comment states that the image does not convey purely factual information, because the image, on its own and without the accompanying text, ''simply shows a man with one eye differently colored than the other'' and ''[t]here is no reason for a consumer to know that the depicted eye-color variation represents 'a large cataract.' '' The comment further states that the warning emphasizes a chronic, non-fatal condition, rather than other conditions with high mortality rates. The comment also states that the warning emphasizes a condition (blindness) that occurs in only a small minority of cataracts.

Another comment states that the image is ''not a reasonable depiction of persons with cataracts'' because the cataract ''would have been treated surgically long before it got to this stage.'' In addition, the same comment asserts that the image ''misleadingly'' makes the cataract look like a cosmetic problem, ''when in reality, '[t]he vast majority of patients who undergo cataract surgery in the [United States] have cataracts that are undetectable by the unaided human eye.' '' Another comment repeats these objections, and one comment notes that cataracts can be treated with ''highly successful cataract surgery and do not result in permanent visual loss.''

One comment asserts that the text and image are not concordant, because the text indicates that smoking can lead to blindness ''[y]et the picture does not clearly indicate that the individual depicted is blind.''

Finally, one comment states that the proposed warning ''seeks to advance FDA's anti-smoking message'' by evoking an emotional response in consumers, because the image ''is discomforting and appears designed to shock the viewer or generate fear at the prospect of experiencing the condition in the image.''

(Response 76) We disagree with comments suggesting that this warning is inaccurate or misleading. As explained at length in the proposed rule, FDA undertook a rigorous, multistep process to develop, test, and refine the textual warning statement, accompanying image, and the overall warning.

The textual warning statement ''WARNING: Smoking causes cataracts, which can lead to blindness'' is factually accurate. As discussed in the proposed rule, the 2004 Surgeon General's Report on cigarette smoking concluded that the evidence is sufficient to infer a causal relationship—the highest level of evidence of causal inferences from the criteria applied in the Surgeon General's Reports—between smoking and cataracts in the lens of the eye (referred to as nuclear cataracts) (Ref. 138). Authors have continued to identify smoking as a major causal risk factor in the development and progression of cataracts (Refs. 195–197). Studies of smoking cessation and risk of cataracts has affirmed that risk decreases, but is not equivalent to never smokers, upon elimination of the exposures of tobacco smoke (Ref. 198).

Additionally, the image in the warning is factually accurate and depicts a common visual presentation of this negative health consequence. The image depicts a close-up of the face of a man aged 65 years or older, which is an appropriate age range for this condition. As stated in the proposed rule (see section VII.A.13 of the proposed rule), prevalence of cataracts among U.S. adults aged 40 years and older in 2010 was estimated to be 17.1 percent by the National Eye Institute (Ref. 199). A study of people affected by cataracts worldwide estimated that in 2010, there were more than 400,000 (range: 240,000 to 850,000) people with cataracts in North America, of whom 13.0 percent (95 percent, CI: 7.8. 19.5) were blind as a result of that cataract (Ref. 200).

FDA disagrees with the comment suggesting that only depictions of conditions with high mortality rates will directly advance Government's interest. As stated in section V.A, the substantial public health burden of cigarette smoking includes individuals with chronic, non-fatal diseases, and therefore FDA has an opportunity to improve public understanding about the negative health consequences of smoking that encompass health conditions beyond those with the highest mortality rates.

FDA also disagrees with the comment suggesting that the image is not a reasonable depiction because persons would have been treated surgically before advancing to the stage depicted. Research has shown that individuals from underserved populations may face barriers to receiving cataract surgery due to factors such as lack of access to medical care, lack of insurance coverage, lack of financial resources, and lack of transportation (Refs. 201 and 202). Thus, it is factually accurate and not uncommon for individuals to experience advanced cataracts as depicted in the image.

Further, the textual warning statement and image are concordant, and the warning is not ambiguous. The textual warning statement explains that smoking causes cataracts, which can lead to blindness. The accompanying concordant and factually accurate image depicts a man with a large cataract caused by smoking. Because the required warning contains the textual warning statement and image paired together, the image aids in understanding the negative health consequence that is the focus of the textual warning statement, and vice versa.

Finally, we disagree with the assertion that the image is intended to evoke an emotional response. The image presents the health condition in a realistic and objective format, does not contain additional unnecessary details (*e.g.,* background setting), and does not contain any elements intended to evoke a negative emotional response.

C. Non-Selected Cigarette Health Warnings

This section discusses the two proposed warnings that FDA is not selecting. In the proposed rule, we indicated that we would make these decisions following our review of public

comments and after weighing additional scientific, legal, and policy considerations. In the following paragraphs, FDA briefly describes the study outcomes for each warning and the comments we received.

1. ''WARNING: Smoking causes COPD, a lung disease that can be fatal [image of diseased lungs].''

As explained in section VI of the proposed rule, FDA included two textual warning statements (''WARNING: Tobacco smoke causes fatal lung disease in nonsmokers'' and ''WARNING: Smoking causes COPD, a lung disease that is fatal'') that were each paired with similar concordant images of diseased lungs. The proposed textual warning statement (''Warning: Smoking causes COPD, a lung disease that can be fatal'') paired with the image of diseased lungs showed strong results in FDA's final consumer research study, showing statistically significant higher ratings across nearly all outcomes. The warning was perceived to be factual by a majority of participants, a result that was not statistically different from the Surgeon General's warnings (*i.e.,* the control condition). Participants who viewed this warning showed improvements in their health beliefs between Sessions 1 and 2, but not between Sessions 1 and 3. To avoid having two identical textual warning statements about COPD and to avoid having two similar, concordant images of diseased lungs paired with different textual warning statements, FDA is not finalizing this cigarette health warning. FDA concludes that having only one required warning statement on COPD reflects the Congressional intent of representing a diverse set of health conditions and furthers the Government's interest in promoting public understanding of the negative health consequences of smoking. In the following paragraphs, FDA briefly describes and responds to the comments received on this proposed warning.

(Comment 77) FDA received numerous comments generally supporting all of the proposed warnings, including this proposed warning. FDA received some comments supporting both proposed warnings related to COPD stating smoking is the number one leading cause of COPD. Other comments, however, oppose this proposed warning, stating that the proposed rule contains no discussion regarding the relationship between smoking and the image in the proposed rule; the warning fails to convey the relationship between cigarette use topography and the depicted image; and that such lung pigmentation is unlikely to occur except after ''many years'' of ''heavy'' smoking. Another comment recommends FDA consider using only one of the two similar images of diseased lungs because studies show that rotating warnings and using a variety of topics and images can improve the effectiveness of warnings.

(Response 77) Although we disagree with the comments that suggest the proposed warning did not adequately convey the relationship between cigarette use and the depicted image, we have elected not to finalize this warning. As we recognized in section VI of the proposed rule, and as at least one comment suggests, it is important that the required warnings use a variety of topics and images. As previously noted, FDA has determined that including one required warning on COPD is consistent with Congressional intent of representing a diverse set of conditions and also advances the Government's interest of promoting greater public understanding of the negative health consequences of smoking.

2. ''WARNING: Smoking causes age-related macular degeneration, which can lead to blindness.''

This proposed textual warning statement on age-related macular degeneration (AMD) is paired with an image of an older man (aged 65 years or older) who is receiving an injection in his right eye to prevent additional vessel growth. This proposed textual warning statement did well in FDA's final consumer research study, showing statistically significant higher ratings across all outcomes except perceived factualness. However, FDA is not finalizing this cigarette health warning because FDA has determined that having only one required warning statement related to blindness reflects the Congressional intent of representing a diverse set of health conditions and furthers the Government's interest in promoting public understanding of the negative health consequences of smoking. In the following paragraphs, FDA briefly describes and responds to the comments received on this proposed warning.

(Comment 78) As with the other proposed warnings, this warning received general support. Several comments (including from state societies of optometric physicians and a national professional medical association for optometric medicine) support the warning but recommend revisions, including that the image should depict the effects of AMD rather than the treatment of the disease, *e.g.,* by using one of the commonly cited images produced by the National Eye Institute depicting a blurred image of a child (as seen from the vantage point of a person with AMD). Some comments also recommend that we change the proposed image of a black man with AMD to a Hispanic woman with AMD, citing data from the National Eye Institute. Other comments oppose this proposed warning, stating that FDA did not assess whether consumers viewing the proposed warning understood the absolute risk of macular degeneration in general, or among smokers. One comment notes that the depiction of treatment of macular degeneration is not accurate as the needle depicted is thicker than one that would actually be used to treat macular degeneration and would not ordinarily be inserted in the center of the eye, as depicted.

(Response 78) We agree with the comments that generally support the inclusion of a cigarette health warning that addresses blindness. Although this proposed warning showed strong results in the final consumer research study, after considering the comments, we have elected not to finalize it. As previously noted, FDA has determined that including one required warning on blindness is consistent with Congressional intent of representing a diverse set of conditions and also advances the Government's interest of promoting greater public understanding of the negative health consequences of smoking.

VIII. Alternatives

In the proposed rule, FDA invited proposals for alternative text and images and requested that any proposals include scientific information supporting that the proposed alternative would, in fact, promote greater public understanding of the negative health consequences of smoking. In response, FDA received a number of comments suggesting text or image edits, and some suggestions for additional required warnings or other changes. As we explain in section VII, we are finalizing 11 of the 13 proposed required warnings after reviewing all the public comments and weighing additional scientific, legal, and policy considerations. We also address in section VII suggestions specific to those required warnings. In the following paragraphs, FDA summarizes other comments we received that suggest additional required warnings or general additions or changes we might consider.

(Comment 79) FDA received several comments suggesting that the required warnings provide additional textual information, such as information on tobacco cessation or Quitlines; information on the positive outcomes of

quitting smoking (or warnings using ''gain-framed'' phrasing); or information on the harmful effects of menthol. Other comments suggest specific warnings FDA should require, in addition to or in place of the required warnings proposed by FDA. For example, one comment suggests that there be a required warning addressing the dangers of tobacco smoke pollution or secondhand smoke, citing information from the CDC (Ref. 203). The comment suggests that the warning state, ''WARNING: Secondhand smoke can cause heart disease and strokes by clogging arteries.'' This comment also suggests adding a warning on breast cancer that states, ''WARNING: Smoking can cause breast cancer, especially in younger women.'' To target young individuals who are image conscious, another comment suggests developing a warning related to how smoking will harm appearance, such as ''WARNING: Using this product will make you look old and wrinkled. Smoking speeds up the aging of skin and causes premature sagging.''

Other comments recommend including additional image elements to the proposed required warnings. For example, one comment suggests use of a hazard alert triangle symbol (*i.e.,* a yellow triangle with an exclamation point in the middle), or the United Nations Globally Harmonized System cancer/chronic health hazard symbol, which is already mandated by the Occupational Safety and Health Administration for chemicals. This comment recommends displaying one or both of these symbols beside the text ''WARNING'' ''both to assist non-English speakers and to make the message more noticeable.'' Another comment recommends that FDA change the background of the warnings to the same yellow used on highway warning signs (*e.g.,* similar to a school zone warning sign), suggesting this would increase the warnings' visibility and strengthen their effectiveness and would more clearly transmit that the required warning is a ''warning.'' One comment suggests FDA adopt a regulation requiring plain packaging of cigarettes with warning labels to eliminate tobacco packaging as a form of advertising and promotion.

Several of the comments frame their suggestions as topics for future rulemakings, with some comments encouraging FDA to begin the process of developing additional cigarette health warnings, in part, as a means to address the concerns of wear out, overexposure, or loss of effectiveness.

(Response 79) As we discuss in section VII, after carefully reviewing the different suggestions that were made, as well as weighing scientific, legal, and policy considerations, FDA is finalizing 11 of the 13 warnings that were included in the proposed rule. In general, no scientific information was submitted to demonstrate that these additional suggested warnings or other suggested changes would improve consumer understanding of the negative health consequences of smoking; not all the suggested health consequences meet FDA's standard for verifying the level of causal inference from the reports of the Surgeon General; and some health topics are already covered by the required warnings. We also note that although one of the nine Tobacco Control Act statements FDA tested in the first consumer research study (''WARNING: Quitting smoking now greatly reduces serious risks to your health''), is a gain-framed message (*i.e.,* one that focuses on the positive outcome of taking an action), this statement is not aligned with this rule's approach to promoting greater public understanding of the negative health consequences of cigarette smoking because its focus is not on understanding of the negative health consequences of smoking. FDA also recognizes that several of these comments suggested that their recommended warnings could require additional notice and another opportunity for public comment.

We discuss concerns related to wear out (or overexposure) in section IX. As explained there, the requirements in § 1141.10(g), namely that required warnings on packages be randomly and equally displayed and distributed and required warnings in advertisements be rotated quarterly in alternating sequence in accordance with an FDA approved plan, will help address the concerns of overexposure and loss of effectiveness over time. Additionally, FDA has authority under section 202(b) of the Tobacco Control Act to conduct future rulemakings as needed to address these concerns if such a change would promote greater public understanding of the risks associated with the use of tobacco products.

IX. Description of the Final Rule—Part 1141

A. Overview of the Final Rule

In the proposed rule, FDA explained that this rule will replace part 1141 in Title 21 of the Code of Federal Regulations. The final rule requires new warnings on cigarette packages and advertisements. Although the proposed rule included 13 required warnings, following our review of the comments on the proposed rule and other considerations, as described in section VII, FDA is finalizing 11 required warnings. The required warnings comprise 11 textual warning statements each accompanied by a color graphic depicting the negative health consequences of smoking. FDA also made clarifications related to the materials that we are incorporating by reference.

The final rule is authorized by section 4 of the FCLAA, as amended by sections 201 and 202 of the Tobacco Control Act, which directs FDA to issue regulations requiring color graphics depicting the negative health consequences of smoking to accompany textual warning statements, and permits FDA to adjust the format, type size, color graphics, and text of any of the label requirements, or establish the format, type size, and text of any other disclosures required under the FD&C Act, if such a change would promote greater public understanding of the risks associated with the use of tobacco products.

In accordance with section 4 of the FCLAA, the final rule directs that a required warning must comprise at least the top 50 percent of the front and rear panels of cigarette packages and at least the top 20 percent of the area of advertisements. The final rule also provides that the required warnings in packages must be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which the product is marketed in accordance with an FDA-approved plan. The required warnings for advertisements must be rotated quarterly in alternating sequence in advertisements for each brand of cigarettes in accordance with an FDA-approved plan. Each tobacco product manufacturer must maintain a copy of the plan and make it available for inspection and copying by officers or employees duly designated by the Secretary. The FDA-approved plan must be retained while in effect and the plan must be retained for a period of not less than 4 years from the date it was last in effect. The required warnings will promote greater public understanding of the negative health consequences of cigarette smoking. The following paragraphs briefly describe the final rule, as well as the comments FDA received and our responses to those comments.

B. Description of Final Regulations and Comments

1. Section 1141.1—Scope

This section establishes that the requirements apply to manufacturers, distributors, and retailers of cigarettes except as described in this section. First, manufacturers or distributors of cigarettes that do not manufacture, package, or import cigarettes for sale or distribution within the United States would not be subject to the rule (proposed § 1141.1(b)). Second, we proposed in § 1141.1(c) that retailers would not be in violation for cigarette packaging that: (1) Contains a warning; (2) is supplied to the retailer by a license- or permit-holding tobacco product manufacturer or distributor; and (3) is not altered by the retailer in a way that is material to 15 U.S.C. 1333 or part 1141. However, this proposed subsection would require that a retailer ensure that all cigarette packages they display or sell contain a warning that is unobscured by stickers, sleeves, or other materials on the packages, for example. Third, we proposed that under § 1141.1(d), the advertisement requirements in proposed § 1141.10 would apply to a retailer only if the retailer is responsible for or directs the warnings for advertising. Retailers would be liable if they display, in a location open to the public, an advertisement that does not contain a warning (proposed § 1141.1(d)). Proposed § 1141.1(d) provided, however, that retailers would be in violation of the FCLAA and this proposed part if they alter cigarette advertising in a way that is material to the requirements, for example, by obscuring or covering up the warning (*e.g.,* blocking with a sticker or marker), shrinking the warning, or using a sleeve to cover the warning.

We received some comments suggesting a different scope, and we summarize those comments and our responses in the following paragraphs. We are finalizing this section without change.

(Comment 80) Many comments suggest that the rule should apply to all nicotine and tobacco products or suggest that FDA implement similar warning labels on non-cigarette tobacco products, such as cigars, smokeless tobacco, and electronic nicotine device systems, in part, because educating the public about the risks of these products would also serve a legitimate public interest.

(Response 80) The FCLAA explicitly applies to cigarettes, and thus it is beyond the scope of this rulemaking to address products other than cigarettes.

(Comment 81) FDA received comments suggesting that the rule should not apply to heated tobacco sticks and, in particular, the heated tobacco product, Heatsticks, used with the IQOS holder. The comments state that that the proposed rule did not explain how the warnings, images, or factual record apply to non-combustible cigarettes or how the required warnings would be accurate and non-misleading applied to these products. Although the comments acknowledge that the product falls within the FCLAA definition of ''cigarette,'' the comments suggest the rule's scope should be limited to combustible cigarettes.

The comments highlight that FDA's communications indicate not all products classified as cigarettes under the FCLAA present the same risk profile, such as language that ''the agency found that the aerosol produced by the IQOS Tobacco Heating System contains fewer toxic chemicals than cigarette smoke, and many of the toxins identified are present at lower levels than in cigarette smoke'' (Ref. 145). Thus, the comments suggest that applying the required warnings to IQOS and Heatsticks would ''undercut [FDA's] important health objectives.''

One comment argues that any rule that does not exempt Heatsticks would violate the APA for three reasons: (1) FDA did not carry its burden of showing the evidence supporting the required warnings applies to Heatsticks (rather FDA's justifications in the proposed rule apply only to traditional, combustible cigarettes); (2) the rule would contradict without explanation FDA's conclusions in the marketing order for Heatsticks; and (3) applying the rule would violate the First Amendment and raise potential concerns under the Takings Clause of the Fifth Amendment (thus, violating the APA). The comment states the proposed rule provides information and evidence only relating to traditional, combustible products and notes that none of the illness or conditions have been causally linked to Heatsticks used with the IQOS device. The comment also indicates that applying the required warnings would depart from FDA's findings in the marketing order and FDA has failed to explain the apparent conflict between the order and the rule by failing to address FDA's previous conclusions regarding the health risks presented by Heatsticks used with the IQOS device.

The comment also states that applying the rule would violate the First Amendment because the required warnings must cover at least the top 50 percent of the front and rear panels of packages and 20 percent of advertisements, and the marketing order requires that 30 percent of the front and rear panels and 20 percent of each advertisement contain a nicotine warning, which would result in 80 percent of packages and 40 percent of advertisements being used for the ''[G]overnment's anti-smoking message.'' This comment also notes this could raise issues under the Takings Clause of the Fifth Amendment.

Both comments also argue that, because the scope of the rule is cigarette smoking, and its goal is to promote greater public understanding of the negative health consequences of smoking, applying the required warnings to Heatsticks would be misleading as this product is a non-combustible product, which produces a nicotine-containing aerosol without combustion, and FDA has acknowledged these are materially different from combustible cigarettes. Given FDA's finding in the premarketing authorization orders that the products are appropriate for the public health, the comments suggest that FDA should tailor the warnings on Heatsticks to contain accurate and non-misleading information. The comments do not propose specific language for this purpose.

(Response 81) As these comments note, heated tobacco sticks are within the FCLAA's definition of cigarette (section 3(1) of the FCLAA), and, as such, are within the scope of the rule. Although IQOS Heatsticks may present different considerations from traditional cigarettes, FDA does not believe that a broad rule requiring cigarette health warnings generally is the appropriate place to address the requirements as they apply to one specific product. Rather, FDA intends to make product-specific decisions about warnings, including decisions about potential product-specific changes to the cigarette health warnings required by this rule, when issuing or revising individual product marketing orders. There is no conflict or inconsistency between the warning regime required by the FCLAA (including its adjustments through this or potential future rulemakings under section 202 of the Tobacco Control Act) and requirements set by a marketing order, because FDA has authority to change the applicability of general warning requirements for a specific product via a marketing order. Among other relevant provisions, section 202(a) of the Tobacco Control Act (amending section 5(a) of the FCLAA) specifically states: ''Except to the extent the Secretary requires *additional or different* statements on any cigarette package . . . *by an order, by an*

authorization to market a product, or by a condition of marketing a product, . . . no statement relating to smoking and health, other than the statement required by section 1333 of this title, shall be required on any cigarette package'' (emphasis added).

This approach allows FDA to review the evidence submitted in an application, including on the health risks of a specific product, and make any appropriate product-specific decisions about warnings based on that product-specific evidence. FDA already conducted such an evaluation in the context of the IQOS premarket tobacco product application (PMTA) marketing authorization order. FDA recognizes that the final rule amends the general warning regime for cigarettes and that FDA will need to consider the applicability of the new regime to the IQOS Heatsticks and revisit the terms of the PMTA order. As stated in the PMTA order, ''[w]hen FDA promulgates a final rule with respect to health warnings for cigarettes, FDA will reevaluate the conditions of marketing with respect to warnings for the products subject to this order.''

2. Section 1141.3—Definitions

Proposed § 1141.3 included definitions for the following terms:

- Cigarette
- Commerce
- Distributor
- Front panel and rear panel
- Manufacturer
- Package or packaging
- Person
- Retailer
- United States

As discussed in the preceding paragraphs, we received some comments regarding the scope of this rulemaking and the definition of ''cigarette,'' which we addressed in those paragraphs. We received no other comments related to these definitions, and we are finalizing this section without change.

3. Section 1141.5—Incorporation by Reference

Proposed § 1141.5 stated that certain material would be incorporated by reference into this part with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. Proposed § 1141.5 provided that all approved material would be available for inspection at the U.S. Food and Drug Administration, the National Archives and Records Administration, as well as available from the Center for Tobacco Products, FDA. Although we did not receive comment on the use of incorporated by reference materials, we did receive comments requesting clarifications on the substance of those materials. In the following paragraphs, we discuss the comments and our responses on this section. After considering the comments, we made clarifications to this section and § 1141.10(b) and (d)(4) and (5) to more clearly state that the materials we are incorporating include the textual warning statement paired with its accompanying color graphic. It is this combination that must be accurately reproduced and meet the requirements of the FCLAA and part 1141. In addition, as described in section VII.B.5, FDA also has increased the contrast and size of the display in one image (''WARNING: Smoking during pregnancy stunts fetal growth'') to improve image clarity. This change is reflected in the material that FDA is incorporating by reference.

The material incorporated by reference, entitled ''Required Cigarette Health Warnings, 2020,'' includes the required warnings (comprising a textual warning statement, as specified in § 1141.10(a), and its accompanying color graphic) in different layouts based on the size and aspect ratio of the display area where the required warning must appear (*i.e.,* on cigarette packages, in cigarette advertisements). We have included an electronic PDF file containing the required warnings as a reference in the docket for the final rule (Ref. 11). FDA is also making this material available on its website at *https://www.fda.gov/cigarette-warning-files.*

FDA recognizes that adaptations to the required warnings may be needed to avoid technical implementation issues due to the varying features, formats, and sizes of cigarette packages and advertisements. To help prevent distortion of the image and text and to minimize the need for adaptation, FDA has created electronic, layered design files, built as .eps files, in different formats and aspect ratios designed to fit packaging and advertising of various shapes and sizes. FDA is not requiring the use of these .eps files, but rather we are providing the files as a resource to assist regulated entities implement part 1141. In addition to the materials incorporated by reference and the .eps files, FDA is making available a technical specifications document that includes information on how to access, select, use, and adapt the appropriate .eps file based on the size and aspect ratio of the display area where the required warning must appear. These .eps files and technical specifications are also available on FDA's website at *https://www.fda.gov/cigarette-warning-files.*

(Comment 82) One comment requests that FDA release final electronic, layered design files for each required warning, as well as technical specifications before the final rule is released.

(Response 82) To assist regulated entities with implementation, we are providing the electronic, layered design files, as well as technical specifications, with the final rule. These materials are available at *https://www.fda.gov/cigarette-warning-files.*

4. Section 1141.10—Required Warnings

a. Section 1141.10(a) and (b)—Required Warnings

In proposed § 1141.10(a) and (b), we proposed to establish required warnings, consisting of one textual warning statement with a specific color graphic to accompany the textual warning statement, which must be accurately reproduced from the materials incorporated by reference in § 1141.5 (proposed § 1141.10(a) and (b)). We received comments on the required warnings, and we discuss those comments and our responses in section VII. After reviewing public comments and weighing additional scientific, legal, and policy considerations, FDA is removing 2 of the 13 required warnings included in the proposed rule, and FDA is finalizing § 1141.10(a) and (b) with 11 required warnings. As described in the preceding paragraphs, FDA is also making clarifying changes to § 1141.10(b) to make it more apparent that it is the combination of a textual warning statement and its accompanying color graphic that we are incorporating by reference and that must be accurately reproduced in the appropriate size and format.

b. Section 1141.10(c)—Packages

We proposed that section 1141.10(c) establish a requirement for packages making it unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any cigarettes unless the package of which bears a required warning in accordance with section 4 of the FCLAA and this part. This section requires that: (1) The required warning must appear directly on the package and must be clearly visible underneath any cellophane or other clear wrapping; (2) The required warning must comprise at least the top 50 percent of the front and rear panels; provided, however, that on cigarette cartons, the required warning must be located on the left side of the

front and rear panels of the carton and must comprise at least the left 50 percent of these panels; and (3) The required warning must be positioned such that the text of the required warning and the other information on that panel of the package have the same orientation. We received comments on these requirements, including a comment that we add an additional requirement under § 1141.10(c). After review and consideration of the comments, FDA is finalizing this subsection without change.

(Comment 83) At least one comment suggests that the required warning on packages be at least 75 percent on the front and rear panels of the package, similar to the approach of other countries, such as Canada and Australia. Additionally, multiple other comments support the provision requiring the warning comprise at least the top 50 percent of the front and rear panels of cigarette packages, stating that this ensures that the required warnings are visible to consumers.

(Response 83) Section 4 of the FCLAA establishes size requirements, and FDA declines to increase the size of the required warnings. Based on the FCLAA, § 1141.10(c)(2) states that the required warnings must comprise at least the top 50 percent of the front and rear panels of the package and that the required warnings must be located on the left side of the front and rear panels of cartons and comprise at least the left 50 percent of these panels.

(Comment 84) FDA received comments from both industry and public health organizations suggesting that the front and rear panels could carry separate warnings (*i.e.,* a different warning on each side). One comment suggests this could provide more information to consumers, and other comments support this as a means of providing some flexibility to manufacturers, given printing and other considerations. Another comment suggests FDA could require warnings in different languages on the front and rear panels of the cigarette package or, through a future rulemaking, FDA could develop two separate images for each warning so that any given package would feature the same warning text on each side but a different depiction.

(Response 84) Section 4(a)(1) of the FCLAA is ambiguous as to whether it mandates the use of the same required warning on both the front and rear panels of the individual cigarette package, or allows two different required warnings to be used, one on the front panel and the other on the rear panel. At this time, we see no reason to mandate that the front and rear panels must carry the same required warnings. Accordingly, the current rulemaking permits manufacturers to use different required warnings if they wish. This is also consistent with Congress's intent that all of the required warnings be displayed in the marketplace at the same time (see section 4(c)(1) and (3) of the FCLAA). As the comments indicate, additional changes such as those suggested (*e.g.,* requiring text in different languages, multiple images for each warning) could be considered in a further rulemaking.

(Comment 85) FDA received a comment suggesting that a subsection (4) be added to § 1141.10(c) to help ensure that the required warnings be unobstructed from view in the retail environment.

(Response 85) FDA declines to make this change as we anticipate that this concern will be adequately addressed by other provisions of the rule, such as § 1141.1(c) and § 1141.1(d). Under § 1141.1(c), a retailer would not be in violation of 1141.10 for packaging that: (1) Contains a warning; (2) is supplied to the retailer by a license- or permit-holding tobacco product manufacturer or distributor; and (3) is not altered by the retailer in a way that is material to 15 U.S.C. 1333 or proposed part 1141. Under § 1141.1(d), the advertisement requirements apply to a retailer only if the retailer is responsible for or directs the warnings for advertising, but this provision does not relieve a retailer of liability if the retailer displays in a location an advertisement that does not contain a warning or that contains a warning that has been altered by the retailer in a way that is material to section 4 of the FCLAA or the requirements of part 1141. As discussed in the proposed rule, retailers would be in violation of the FCLAA and part 1141 if they alter cigarette packaging or advertising in a way that is material to these requirements. This could, for example, occur if a retailer obscures or covers the required warning (*e.g.,* blocking with a sticker or marker), shrinks the warning, or uses a sleeve to cover the warning. Retailers also would be liable if they display, in a location open to the public, an advertisement that does not contain a warning.

c. Section 1141.10(d)—Advertisements

We proposed that § 1141.10(d) establish that it is unlawful for any manufacturer, distributor, or retailer of cigarettes to advertise or cause to be advertised within the United States any cigarette unless each advertisement bears a required warning in accordance with section 4 of the FCLAA and part 1141. The proposed requirements provide, in part, that: (1) For print advertisements and other advertisements with a visual component (including, for example, advertisements on signs, retail displays, internet web pages, digital platforms, mobile applications, and email correspondence), the required warning must appear directly on the advertisement; and (2) the required warning must comprise at least 20 percent of the area of the advertisement in a conspicuous and prominent format and location at the top of each advertisement within the trim area, if any.

In addition, we proposed in § 1141.10(d)(3) that the text in each required warning must be in the English language, except in the case of an advertisement that appears in a non-English medium, the text in the required warning must appear in the predominant language of the medium whether or not the advertisement is in English, and in the case of an advertisement that appears in an English language medium but that is not in English, the text in the required warning must appear in the same language as that principally used in the advertisement. We also proposed in § 1141.10(d)(4) and (5) that for English-language and Spanish-language warnings, each required warning must be obtained from the electronic files contained in ''Required Cigarette Health Warnings,'' which would be incorporated by reference at § 1141.5, and be accurately reproduced as specified in ''Required Cigarette Health Warnings,'' and for non-English-language warnings, other than Spanish-language warnings, each required warning must be obtained from the electronic files contained in ''Required Cigarette Health Warnings,'' which would be incorporated by reference at § 1141.5, and be accurately reproduced as specified in ''Required Cigarette Health Warnings,'' including the substitution and insertion of a true and accurate translation of the textual warning statement in place of the English language version. The inserted textual warning statement must comply with the requirements of section 4 of the FCLAA, including area and other formatting requirements, and this part.

In the following paragraphs, we discuss comments on these provisions. After carefully considering the comments, we are finalizing these provisions without substantive change; however, as described earlier in this section, we made clarifications to § 1141.10(d)(4) and (5) to make it more apparent that it is the combination of a textual warning statement and its

accompanying color graphic that we are incorporating by reference and that must be accurately reproduced in the appropriate size and format.

(Comment 86) Several comments note general support for the provision requiring that the required warning comprise at least 20 percent of the area of the advertisements stating that it is sufficient to ensure the required warnings are visible to consumers. FDA also received a comment requesting that we consider adding price promotions and coupons to the examples provided in § 1141.10(d) because many apps, mailers, and pop up ads contain only coupons or price promotions, like quick response codes.

(Response 86) FDA agrees with the general support for these provisions. We note that the list of examples included in this provision is not intended to be exhaustive, and that the requirements under part 1141 apply to all forms of cigarette advertising, regardless of the medium in which it appears. The final rule applies to advertisements appearing in or on, for example, promotional materials (point-of-sale and non-point-of-sale), billboards, posters, placards, published journals, newspapers, magazines, other periodicals, catalogues, leaflets, brochures, direct mail, shelf-talkers, display racks, internet web pages, electronic mail correspondence, or be communicated via mobile telephone, smartphone, microblog, social media website, or other communication tool; websites, applications, or other programs that allow for the sharing of audio, video, or photography files; video and audio promotions; and items not subject to the sale or distribution restriction in § 1140.34. We agree that the requirement that the required warning comprise at least 20 percent of the area of the advertisement in a conspicuous and prominent format and location at the top of each advertisement within any trim area will help ensure the warnings are visible to consumers.

(Comment 87) Some comments address the translation of the textual warning statements into languages other than Spanish and express concerns that manufacturers or retailers might undermine the effectiveness of the required warning by using a language in the warning that is not appropriate to the audience reading or experiencing the advertisement. A comment suggests that if FDA does not provide warning translations in languages other than English and Spanish, then FDA should review any translated warning before the product can be advertised. Another comment recommends that FDA provide the translation of textual warning statements into languages most commonly used, other than English, to help ensure access to this information as a health equity measure.

(Response 87) Although we decline to provide additional translations, FDA does intend to monitor translations to ensure that they are accurately reproduced and will take action, as appropriate, to address any translations that do not meet the requirements of the FCLAA and the final rule. Under § 1141.10(d)(5) all non-English-language warnings, other than Spanish-language warnings, must be accurately reproduced as specified in ''Required Cigarette Health Warnings, 2020,'' including the substitution and insertion of a true and accurate translation of the textual warning statement in place of the English language version. If a translation of a textual warning statement is not a true and accurate translation, as required by § 1141.10(d)(5), the cigarette will be deemed to be misbranded under section 903(a)(1) or 903(a)(7)(A) of the FD&C Act for failure to bear one of the required warnings in accordance with section 4 of the FCLAA and this part.

d. Section 1141.10(e) and (f)—Other Requirements

In the proposed rule, § 1141.10(e) states that the required warnings must be indelibly printed on or permanently affixed to the package or advertisement. Proposed § 1141.10(f) establishes that no person may manufacture, package, sell, offer for sale, distribute, or import for sale or distribution within the United States cigarettes whose packages or advertisements are not in compliance with section 4 of the FCLAA and this part, except as provided by § 1141.10(c) and (d). We received no comments regarding these specific proposed provisions and are finalizing § 1141.10(e) and (f) without change.

e. Section 1141.10(g)—Cigarette Plans

Section § 1141.10(g)(1) proposed that the required warnings for packages must be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which the product is marketed in accordance with a plan submitted by the tobacco product manufacturer, distributor, or retailer to, and approved by, FDA. In addition, proposed § 1141.10(g)(2) provides that the required warnings for advertisements must be rotated quarterly in alternating sequence in advertisements for each brand of cigarettes in accordance with a plan submitted by the tobacco product manufacturer, distributer, retailer to, and approved by, FDA. Under proposed § 1141.10(g)(3), FDA will review each plan submitted under this section and approve it if the plan: (1) Will provide for the equal distribution and display on packaging and the rotation required in advertising under this subsection and (2) assures that all of the labels required under this section will be displayed by the tobacco product manufacturer, distributor, or retailer at the same time. Under proposed § 1141.10(g)(4) each tobacco product manufacturer required to randomly and equally display and distribute warnings on packaging or rotate warnings in advertisements in accordance with an FDA-approved plan under section 4 of the FCLAA and this part must maintain a copy of such FDA-approved plan and make it available for inspection and copying by officers or employees duly designated by the Secretary of Health and Human Services. The FDA-approved plan must be retained while in effect and for a period of not less than 4 years from the date it was last in effect.

After considering the comments on § 1141.10(g), we are finalizing this provision without change. We discuss both the comments and our responses in the following paragraphs.

(Comment 88) Some comments express general support both for the rotation requirements to reduce the risk of wear out and overexposure and for the submission of plans for approval by FDA. These comments encourage FDA to have in place robust compliance processes to assess whether manufactures, distributors, and retailers are meeting the requirements of this rule. Some comments note that ''particular attention'' be directed toward media and retailers serving people of color, people with low incomes, and LGBTQ populations.

(Response 88) We agree that the requirements related to cigarette plans are important to implementing the requirements of the FCLAA. The required warnings on packages must be randomly displayed and distributed in accordance with an FDA-approved plan. Similarly, the required warnings for advertisements must be rotated quarterly in alternating sequence in advertisements, in accordance with an FDA-approved plan. Each tobacco product manufacturer must maintain a copy of the plan and make it available for inspection and copying by officers or employees duly designated by the Secretary. A cigarette will be deemed to be misbranded under section 903(a)(1) or 903(a)(7)(A) and (8) of the FD&C Act if its package or advertising does not bear one of the required warnings in

accordance with section 4 of the FCLAA and this part. We further discuss the importance of enforcing these requirements in later paragraphs of this section (see section IX.B.6).

(Comment 89) Two comments raise concerns related to satisfying the ''random and equal'' requirement of proposed § 1141.10(g) for 13 different warnings without significant changes to packaging production. These comments note that because 13 is both a prime and odd number, printing 13 different warnings equally is incompatible with industry-wide printing practices. One comment suggests that FDA either require a random and equal distribution of 12 or 9 warnings or random but unequal display of 13 warnings. The other comment proposes that FDA require 9 different warnings and provide greater flexibility for the random and equal requirement because of printing method variation across the industry.

(Response 89) FDA is requiring 11 warnings, which we appreciate is also a prime and odd number and thus may present similar issues. We address some of these issues in section X. In addition, by permitting the front and rear panels to carry different warnings, the rule may mitigate some of these issues by giving manufacturers flexibility in how they meet the requirements of the rule. We also note that the FCLAA provides that the required warnings be ''randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product,'' which we believe provides for some flexibility in the meaning of ''equal,'' as defined below. Manufacturers with concerns about complying with this requirement should promptly reach out to FDA to discuss their approach for reasonably achieving the random and equal display and distribution of the required warnings, in as equal a number of times as is possible, and any other specific concerns or circumstances regarding this requirement. We encourage manufacturers to submit their cigarette plan to FDA as soon as possible so that we can discuss these concerns and consider proposals with manufacturers in a timely manner. FDA intends to issue a final guidance document with additional information and recommendations that may be helpful in preparing these plans, which, when issued, may be found at *https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/guidance.*

(Comment 90) Comments also raised concerns about satisfying the ''random and equal'' requirement within the 12-month period prescribed by proposed § 1141.10(g)(1), which states each required warning would be required to be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product. These comments asked for clarification of the phrase ''as is possible'' and asked for flexibility in achieving ''equal distribution.'' At least two comments suggest a deviation allowance of 4 percent (or larger). These comments also note the difficulty of achieving equal distribution within the 12-month period specified and asked for a longer period in which to achieve equal distribution, suggesting that achieving the random and equal requirement within the 12-month period would be particularly challenging for products with low annual volume sales.

(Response 90) We recognize and understand the difficulties in achieving the random and equal display requirement within a 12-month period given the number of required warnings and agree that some level of deviation is appropriate particularly given the language of the FCLAA, which includes the phrase ''as equal a number of times as is possible.'' The cigarette plan for packaging should include a discussion of how the requirements are to be implemented based on the specific manufacturing processes and distribution procedures to ensure random display, in as equal a number of times as is possible, in each 12-month period on each brand of the product. Manufacturers with concerns about complying with this requirement for their products should promptly reach out to FDA to discuss their approach and proposal for reasonably achieving the random and equal display and distribution of the required warnings, in as equal a number of times as is possible, and any other specific concerns or circumstances regarding this requirement. We encourage manufacturers to submit their cigarette plan to FDA as soon as possible so that we can discuss these concerns and consider proposals with manufacturers in a timely manner. Additionally, FDA intends to issue a final guidance document with additional information and recommendations that may be helpful in preparing these plans, which, when issued, may be found at *https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/guidance.*

(Comment 91) One comment requests that FDA accept in digital files (*i.e.,* electronic art) the representative samples of packages and advertisements with each of the required warnings submitted with cigarette plans as FDA does for biannual tobacco product listing submissions. The comment notes that this would allow plans to be prepared quickly without the expense of engraving cylinders and obtaining proofs for each brand style. The comment also notes that the submission of physical packages would also be time-consuming, whereas the use of digital files would allow companies to more quickly respond without the time and expense of re-engraving cylinders.

(Response 91) FDA agrees that it is acceptable to voluntarily submit representative advertisements and packaging as digital files (*i.e.,* electronic art) along with other information that the manufacturer elects to submit with the cigarette plan to ensure that it is complete. The information submitted should describe a plan to achieve the random and equal display and distribution of the required warnings on packages and the quarterly rotation of the required warnings in advertisements. As discussed in the section IX of the proposed rule, FDA is only requesting that the cigarette plan include representative samples of packages and advertisements with each of the required warnings. The samples are to place the cigarette plan in context and facilitate FDA's review of the plan. FDA's review of a cigarette plan is only for the purpose of determining compliance with the statutory and regulatory criteria for approval of a cigarette plan, as set forth in section 4(c)(3) of the FCLAA and proposed § 1141.10(g)(3). Approval of a cigarette plan does not represent a determination by FDA that any specific package or advertisement complies with any of the other requirements under section 4 of the FCLAA and part 1141, or any other requirements under the FD&C Act and its implementing regulations. Additionally, FDA intends to issue a final guidance document with additional information and recommendations that may be helpful in preparing these plans, which, when issued, may be found at *https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/guidance.*

(Comment 92) FDA also received at least one comment requesting FDA clarify in the final rule that retailers are not required to submit plans for random and equal display of the required warnings for packages and quarterly rotation of the required warnings in advertisements. The comment notes that requiring retailers to submit a plan exceeds FDA's authority, would unduly burden retailers, and is not achievable as retailers have no control over which heath warning is displayed as they receive the cigarette packages that they sell, and often the advertisements they use, from tobacco product manufacturers and distributors.

(Response 92) With respect to the concerns related to retailers, § 1141.1(c) and (d) explain when a retailer is not in violation of the FCLAA and § 1141.10. Under § 1141.1(c), retailers typically would not be required to submit a cigarette plan for packaging, as long as the cigarette packaging: (1) Contains a warning; (2) is supplied to the retailer by a license- or permit-holding tobacco product manufacturer or distributor; and (3) is not altered by the retailer in a way that is material to 15 U.S.C. 1333 or part 1141 (see § 1141.1(c)). We believe most, if not all, retailers would fall under this scenario. Retailers who are also manufacturers will be subject to both the requirements for retailers and manufacturers, as applicable. Retailers that are responsible for or direct the warnings for advertising will be required to submit a cigarette plan for advertising and would be subject to the advertisement requirements set forth in § 1141.10(d). We note, however, this provision will not relieve a retailer of liability if the retailer displays in a location open to the public an advertisement that does not contain a warning or that contains a warning that has been altered by the retailer in a way that is material to section 4 of the FCLAA or the requirements of this proposed part.

We discuss these provisions in more detail in the section IX of the proposed rule. In general, based on FDA's experience reviewing plans for other tobacco products, we believe it is likely that for domestic products only one cigarette plan will be submitted for each brand and that the brand's manufacturer will submit this plan because, in most instances, the brand's manufacturer is the entity best able to ensure that a plan meets the relevant requirements. The brand's manufacturer is also typically the entity responsible, either directly or through a contractor or other agent, for placing or directing the placement of the required warnings on the brand's cigarette packages and for directing distribution. For cigarettes that are imported, the importer (included in the definition of manufacturer) usually directs distribution of the packages after they are imported. Therefore, for imported cigarettes, the importer is likely best-positioned to submit the plan. To further aid in the understanding of the cigarette plan requirements, FDA intends to issue a final guidance document with additional information and recommendations that may be helpful in preparing these plans, which, when issued, may be found at *https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/guidance.*

5. Section 1141.12—Misbranding of Cigarettes

Under proposed § 1141.12 a cigarette would be deemed to be misbranded under section 903(a)(1) of the FD&C Act if its package does not bear one of the required warnings and will be deemed to be misbranded under section 903(a)(7)(A) of the FD&C Act if its advertising does not bear one of the required warnings in accordance with section 4 of the FCLAA and this part. In addition, under proposed § 1141.12(b) a cigarette advertisement and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor would be deemed to include a brief statement of relevant warnings for the purposes of section 903(a)(8) of the FD&C Act if it bears one of the required warnings in accordance with section 4 of the FCLAA and this part. A cigarette distributed or offered for sale in any State shall be deemed to be misbranded under section 903(a)(8) of the FD&C Act unless the manufacturer, packer, or distributor includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to the cigarette one of the required warnings in accordance with section 4 of the FCLAA and this part. We received no comment regarding proposed § 1141.12, and we are finalizing this section without change.

6. Other Comments—Compliance

(Comment 93) FDA received some general comments related to enforcement of the rule. These comments encourage FDA to ensure enforcement of the required warnings on packages and advertisements particularly in neighborhoods of low SES. The comments suggest that surveillance and fines may improve compliance. Other comments recommend that FDA be mindful of vendors who, although illegal, might sell merchandise such as from their backpacks.

(Response 93) FDA agrees that enforcing warning requirements is important. FDA conducts routine monitoring and surveillance of the manufacturing, marketing, sales, distribution, labeling, advertising and other promotional activities of regulated tobacco products for compliance with applicable provisions of the FD&C Act. FDA has a range of tools to help ensure compliance with tobacco product regulations. Failure to comply with the FCLAA, FD&C Act, or their implementing regulations may result in FDA initiating action, including, but not limited to, warning letters, civil money penalties, no-tobacco-sale orders, seizures, injunction, or criminal prosecution. Additionally, misbranded tobacco products offered for import into the United States are subject to detention and refusal of admission.

(Comment 94) Another comment also suggests that FDA require manufacturers to submit inventory information, including information on levels of inventory and when it is expected to be sold, as a means of distinguishing cigarette packages sold from existing inventory from inventory manufactured after the effective date. The comment recommends FDA ask for information on how to read date codes to help the Agency better understand which manufacturers may not be complying with the rule.

(Response 94) FDA declines to adopt these suggestions as section 201(b) of the Tobacco Control Act imposes a requirement that, beginning 30 days after the effective date of the final rule, manufacturers would not be permitted to introduce into domestic commerce any cigarette packages that do not contain the required warnings, irrespective of the date of manufacture. FDA believes this requirement addresses the concern related to ensuring compliance with the required warnings.

X. Comments Regarding Implementation Issues

Some comments raise questions related to implementing the requirements of the final rule. We describe and address those comments in the following paragraphs.

(Comment 95) FDA received comments objecting to the proposed rule as based on a fundamental misunderstanding of the processes used to print the vast majority of cigarette packaging in the United States, which one comment states is a gravure process using engraved cylinders. These comments state the rule would place significant and unnecessary burdens on industry because the requirement of random and equal display and distribution is infeasible.

(Response 95) We disagree that the rule is based on a fundamental misunderstanding of the processes used to print the vast majority of cigarette packaging in the United States. We respond to this particular concern in more detail in the Final Regulatory Impact Analysis that is issuing with the final rule (Ref. 16), but we note generally that (contrary to the

comment's suggestion) FDA's Labeling Cost Model does assume that 95 percent of cigarette UPCs will be printed using the gravure method.

In addition, we recognize and understand that achieving conformity with the narrowest possible reading of the random and equal display requirement within a 12-month period would pose some difficulties, and we agree that allowing some level of deviation is appropriate particularly given the language of the FCLAA, which includes the phrase ''as equal a number of times as is possible.'' As we discuss in section IX, the cigarette plan for packaging should include a discussion of how the requirements are to be implemented based on the specific manufacturing processes and distribution procedures to ensure random display, in as equal a number of times as is possible, in each 12-month period on each brand of the product. Manufacturers with concerns about complying with this requirement for their products should promptly reach out to FDA to discuss their approach and proposal for reasonably achieving the random and equal display and distribution of the required warnings, in as equal a number of times as is possible, and any other specific concerns or circumstances regarding this requirement. We encourage manufacturers to submit their cigarette plan to FDA as soon as possible so that we can discuss these concerns and consider proposals with manufacturers in a timely manner. Additionally, FDA intends to issue a final guidance document with additional information and recommendations that may be helpful in preparing these plans, which, when issued, may be found at *https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/guidance.*

(Comment 96) One comment requests ''Printer's Proofs'' for each required warning to facilitate consistent reproduction of the color images. The comment notes that manufacturers use different ink application techniques and substrates, which could result in altered appearances of the warnings on packs.

(Response 96) FDA intends to provide Printer's Proofs upon request. Regulated entities can request a set of SWOP or GRACoL Printer's Proofs for the required warnings (each set will contain a total of 22 proofs: The 11 required warnings with black text on white backgrounds and the 11 required warnings with white text on black backgrounds). Requests can be submitted by email (*cigarettewarningfiles@fda.hhs.gov*), phone (1–877–CTP–1373) or regular mail (Food and Drug Administration, Center for Tobacco Products, Document Control Center, Building 71, Room G335, ATTN: Office of Health Communication and Education, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002).

(Comment 97) One comment discusses a challenge with accurately reproducing the required warnings on a variety of cigarette package shapes and sizes. The company asked that FDA provide specific direction for permissible adjustments to the required warnings and that FDA tolerate minor variances in how the warnings appear on cigarette packaging.

(Response 97) As discussed in section IX.B.3, we are providing the required warnings in a variety of sizes and formats as incorporated by reference materials. In addition, we are providing electronic, layered design files in an .eps format, which manufacturers may use in developing their packaging and labeling, as well as technical specifications to selecting, using, and adapting these files. These documents will provide extensive information and help manufacturers accurately reproduce the required warnings for different packages shapes and sizes.

(Comment 98) One comment requests that FDA clarify how manufacturers should incorporate the required warnings on packs with hinged lids. The comment states that the content of warnings printed on the hinged lids can shift up or down by about 1 mm at the point where the lid meets the front of the pack due to normal variations in production of the packaging. These comments recommend that FDA design the warnings with all text located either above or below the hinged lid, allow for minor variations in how the required warnings appear on cigarette packs due to this manufacturing variability, or provide font suitcases and instructions for use that allow manufacturers to flow text freely within a designated text area to ensure that the text is not interrupted.

(Response 98) To ensure that the warning is clear and legible on hinged lid packages, FDA is allowing for minor variations in how the required warnings appear. Manufacturers can separate two lines of text within the textual warning statement such that the line at the location where the lid is to open cuts across the background space between two lines rather than through a line of text. This will help ensure that the textual warning statement is not severed when the package is opened and is clear, conspicuous, and legible in accordance with section 4 of the FCLAA. We note that product packages with hinged lids are widely prevalent in countries that already require pictorial cigarette warnings and, based on that experience, we conclude that this new provision should provide companies with flexibility for displaying the warnings on packages with hinged lids.

(Comment 99) One comment requests that FDA allow manufacturers to position warnings below soft pack closures. The comment explains that the top of a cigarette soft pack is folded down and held down by an adhesive closure that is applied after the packages have been printed. Without any accommodation, that closure would obstruct a portion of the required warnings. The comment notes that in FDA's 2011 rulemaking, the Agency permitted manufacturers to ''adapt the warnings on 'soft pack' style packaging by moving the warning below the closure'' (76 FR at 36691), but the comment asserts that the 0.375 inch boundary that FDA previously contemplated is too small to ensure there is enough adhesive for the package to remain closed while accounting for standard printing variations. Instead, the comment requests that FDA should allow the closure to extend up to 0.482 inches from the top of the edge of the package.

(Response 99) FDA disagrees. As in 2011, we recognize the technological difficulty of incorporating the required warnings on ''soft pack'' style packaging. Given the paramount need to incorporate the warning without obstructing any of the elements of the warning (*i.e.,* the image and the textual warning statement), a company may adapt the warnings on ''soft pack'' style packaging by moving the warning below the closure. Because of the importance of maintaining the integrity of the required warning (*e.g.,* not distorting the image or text), an adaptation of 0.375 inches may be acceptable only when it is not technologically feasible to incorporate the required warnings on ''soft pack'' style packaging without the need to adapt the required warning and the required warning after the adaptation is still accurately reproduced (*e.g.,* the required warning is not distorted). Anything in excess of 0.375 inches may begin to distort the required warning and likely would not be in compliance with the requirements of the FCLAA and part 1141. We strongly encourage manufacturers to reach out to us to discuss these issues.

Under this approach, companies using ''soft pack'' style packaging could move only the upper boundary of the display area of the warning so that it runs along a line that is parallel to and not more than 0.375 inches from the top edge of the package. The companies may compress the vertical size of the

image and then shift it down (so that it stays within the top 50 percent of the package), but companies who do this must ensure that, to the extent the required warning must be adapted to fit the dimensions of the warning area below the closure, the proportions of the required warning must be maintained. In addition, the closure and the portion of the packaging that appears between the top edge of the package and the upper boundary of the display area of the required warning must be either solid black or solid white. This will allow companies to continue to produce ''soft pack'' style packaging with closures at the top center of the pack without obstructing the required warning. However, if we determine that it would be technologically feasible to incorporate the required warnings on ''soft pack'' style packaging without the need to adapt the warning in this way, we plan to notify the regulated companies and the public of this conclusion and give regulated companies a reasonable amount of time to modify their packaging before any regulatory action is taken under this rule.

(Comment 100) Some comments request clarifications on implementing the advertising requirements when the advertisement is what they call ''small'' or digital. For example, one comment notes that the proposed rule does not provide clarification regarding the display of warnings in digital advertisements. The comment asks that FDA evaluate existing digital platforms and provide specific direction on how to display the required warnings based on specific devices and software prior to finalizing the final rule. Another comment notes challenges related to displaying the warnings on small advertisements in a way that is not illegible or distorted. This comment suggests that FDA exempt small advertisements from the warning requirements or revise the minimum font requirements and use an appropriate image specifically designed for small formats.

(Response 100) Although FDA acknowledges that implementing the requirements for certain small advertisements and some digital advertisements may present specific challenges in certain cases, we decline to exempt small advertisements. In both the case of digital advertisements or small advertisements, FDA invites manufacturers to raise the specific implementation issue they have as part of the submission of the plan under § 1141.10(g) to facilitate a solution that reflects the requirements and is also technically feasible for the manufacturer or other responsible entity.

XI. Effective Dates

In the proposed rule, FDA proposed that the required warnings for packages and advertisement become effective 15 months after the date the final rule publishes in the **Federal Register**, consistent with the language of section 201(b) of the Tobacco Control Act. FDA also proposed an effective date for the submission of plans under § 1141.10(g) of no later than 5 months after the final rule publishes in the **Federal Register**. Section 201(b) of the Tobacco Control Act provides that, beginning 30 days after the effective date, a manufacturer must not introduce into domestic commerce of the United States any product, irrespective of the date of manufacture, that is not in conformance with section 4 of the FCLAA, as amended by the Tobacco Control Act. As provided by section 201(b) of the Tobacco Control Act, after the 30-day period, manufacturers would not be permitted to introduce into domestic commerce any cigarette packages that do not contain the required warnings, irrespective of the date of manufacture. In the proposed rule, we also requested comments regarding ways to differentiate cigarette packages sold from existing inventory from those that were manufactured after the effective date.

We received comments on both of these proposed effective dates, as well as the 30-day period. Following consideration of the comments as described below, the final rule continues to include an effective date of 15 months from the date the final rule publishes in the **Federal Register**, as required by section 201(b) of the Tobacco Control Act. However, after further consideration, we are no longer including a 5-month effective date for the submission of cigarette plans to FDA. The FCLAA and § 1141.10(g) require manufacturers to submit plans for the display and distribution of required warnings on cigarettes packages and the rotation of required warnings on cigarette advertising and to obtain FDA approval of their plans before products required to bear such warnings enter the market. Therefore, we strongly encourage entities to submit cigarette plans as soon as possible after publication of this final rule, and in any event within 5 months after the publication of this final rule. In addition, as directed by section 201(b) of the Tobacco Control Act, after the 30-day period, manufacturers will not be permitted to introduce into domestic commerce any cigarette packages that do not contain the required warnings, irrespective of the date of manufacture.

(Comment 101) Some comments identify a challenge with complying with the implementation deadline of 15 months after publication of the final rule. These comments note that once the final rule is published it will take time to redesign packaging to include the new required warnings, submit plans to FDA for review, work with printers to develop printing processes to print the new required warnings in accord with their approved plans, and then print new packs. These comments request an extension of the 15-month deadline, that FDA toll (*i.e.,* pause) the deadline during the Agency's review of the rotational plans, or both, or that FDA use enforcement discretion to allow companies greater than 15 months to come into compliance. A comment suggests FDA is obligated to determine the length of time it will take manufacturers to engrave cylinders and print labels and provide a sufficient amount of time to comply with the rule. This comment notes that the number of cylinders that need to be engraved will depend on the number of required warnings, which could result in thousands of cylinders, that there are two main printing companies used by the industry, that manufacturers may need additional time to redesign their labels to use fewer colors, and lastly, that manufacturers cannot get a head start because of uncertainty around the rule surviving constitutional challenge or being subject to severability. One comment requests that FDA clarify that ''distributors and retailers can continue to distribute and sell for an unlimited sell-through period products manufactured before the effective date and introduced into commerce by the manufacturer within 30 days of the effective date.'' This comment asserts that small tobacco product manufacturers cannot afford the hardship of product returns by distributors and retailers who may be uncertain of their ability to sell products that do not bear the required warnings.

Other comments encourage the Agency to maintain the proposed rule's timelines for implementation (*e.g.,* submitting cigarette plans no later than 5 months after publication of the final rule and implementing the warnings no later than 15 months after publication of the final rule) as they are reasonable and consistent with the FCLAA, especially given the time that has elapsed since the issuance of the initial rule in 2011 and that the public has been deprived of the benefits of the required warnings for almost a decade due to FDA's slow response in proposing this rule. These

comments note that industry has been on notice of the required warnings since the enactment of the Tobacco Control Act and manufacturers have implemented pictorial cigarette warnings in more than 100 other countries.

(Response 101) We agree with the comments that suggest we maintain the proposed 15-month deadline for the effective date of the required warnings, consistent with the Tobacco Control Act. Consistent with the statute, we believe it is also important to maintain the 30-day period after which products may not be introduced into domestic commerce by the manufacturer, and we disagree that further clarification of this is necessary. Although we acknowledge that there may be some challenges as industry moves to implement these requirements, FDA intends to assist manufacturers, distributors, and retailers, as applicable, with specific questions and concerns regarding these requirements. Manufacturers with concerns about complying with this requirement for their products should reach out to FDA to discuss their approach and proposal for reasonably achieving the random and equal display and distribution of the required warnings, in as equal a number of times as is possible, and any other specific concerns or circumstances regarding compliance with the warning requirements.

Section 201(a) of the Tobacco Control Act requires manufacturers to submit plans for the display and distribution of required warnings on cigarettes packages and the rotation of required warnings on cigarette advertising, and to obtain FDA approval of their plans before products required to bear such warnings enter the market. Therefore, for products that will be on the market as of the effective date of the required warnings, manufacturers must submit, and FDA must approve, their plans ahead of the required warnings' effective date. FDA strongly encourages entities to submit cigarette plans as soon as possible after publication of this final rule, and in any event within five months after publication of this final rule. Doing so will benefit regulated industry, based on the comments the Agency received regarding the time firms may need to work with printers to implement the required warnings as outlined in their approved plans. Early submission will facilitate timely FDA review prior to the effective date of the required warnings, encourage dialogue with entities regarding any implementation concerns, and provide time to consider proposals by entities in a timely manner. Given the initial high volume of original submissions FDA may receive and based on our experience with review of plans for required warnings on other tobacco products, our best estimate is that it will take up to 6 months for the Agency to review those original submissions. FDA will ensure that its review of cigarette plans will be completed no later than 6 months after receipt of an adequate plan from persons who work in good faith with FDA to complete its review (*e.g.,* persons should work diligently with FDA and be responsive by submitting any requested information in a timely manner). If there is a higher volume of submissions received than currently expected, for those entities who submit an adequate plan within 5 months of publication of this final rule and who work in good faith with FDA to complete its review, FDA intends to ensure that entities are not delayed or prevented from distributing cigarette packages or advertising their products due to the Agency's not having approved their plans by the effective date of the final rule. In addition, FDA intends to issue a final guidance document that is intended to assist entities with developing their cigarette plans, which, when issued, may be found at *https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/guidance.*

XII. Severability

Consistent with section 5 of the Tobacco Control Act, FDA intends for the various requirements established by this rulemaking to be severable. Section 5 of the Tobacco Control Act states that, if any provision of a regulation issued under the Tobacco Control Act is held to be invalid, the remainder of the regulation ''shall not be affected and shall continue to be enforced to the fullest extent possible.'' (Section 5 of the Tobacco Control Act is codified at 21 U.S.C. 387 note.) FDA has concluded that the individual aspects of this rule are workable on their own and should go forward in the event that some are invalidated. As discussed below, FDA has determined that severability both is consistent with Congressional intent and would best advance the Government's interest in promoting greater public understanding of the negative health consequences of cigarette smoking.

The rule is sound in its entirety and should be upheld in full. However, in a circumstance where some but not all of the rule's provisions are invalidated, FDA's intent is for the other provisions to go into effect. A key question to determining severability is whether the remaining portions of a regulation ''could function sensibly without the stricken provision.'' *MD/DC/DE Broadcasters Ass'n* v. *F.C.C.,* 236 F.3d 13, 22 (D.C. Cir. 2001). Here, FDA has considered each provision independently and concluded that the individual portions of this rule are workable on their own.

In the event that some portions of the rule are stricken, FDA has concluded that each other portion of the rule would ''function sensibly'' on its own and should go into effect. As the proposed rule indicated, if a court were to invalidate some of the cigarette health warnings (*i.e.,* text-and-image pairings), but some of the pairings remained valid, FDA intends that the remaining required warnings would go into effect. As another example, if a court were to invalidate some but not all of the images within the cigarette health warnings, FDA intends that those images would be severed and the corresponding textual warning statements would go into effect without the invalidated images, along with the remaining cigarette health warnings that pair a textual warning statement with an image. As a third example, if a court were to invalidate all of the images within the cigarette health warnings, FDA intends for the invalidated images to be severed and all the warnings to go into effect with only their textual warning statements.

Among other things, FDA has considered the statute's rotation and distribution requirements in reaching its conclusion that all portions of the rule can function sensibly and should take effect if any portions are invalidated. In the event that any warnings specified in this final rule do not go into effect, the requirements for warnings to be randomly and equally displayed and distributed on packages and quarterly rotated in advertisements will be applied to the remaining warnings, such as remaining text-and-image pairings or textual warning statements without images.

FDA's intent for any invalidated portions of the rule to be severed also advances Congress's intent to replace the stale 1984 Surgeon General's warnings and to promote greater public understanding of the negative health consequences of cigarette smoking, since the remaining warnings could go into effect much earlier than could any different warnings implemented by other, subsequent means, such as further Agency rulemaking.

Several comments made remarks supporting or opposing the severability of the rule's provisions.

(Comment 102) One comment objects to any severing of the rulemaking because it asserts that FDA did not

justify each permutation presented in the proposed rule, and severing the rulemaking would deny interested parties sufficient notice to participate in a meaningful notice and comment process. The comment suggests that section 5 of the Tobacco Control Act does not mandate severing the rulemaking in this situation. In addition, one comment states that because the Tobacco Control Act mandates that the textual warning statements must be accompanied by color graphics, FDA does not have the discretion to implement the textual warning statements only. This comment asserts that FDA is not authorized to change the placement of the warnings or reduce the statutory 50 percent size requirement. Another comment stated that implementation of only portions of the regulation would not be workable from a practical standpoint of rotating, distributing, and displaying the required warnings on cigarette packages and advertisements.

In contrast, other comments support severability, arguing that should any portion of the rule be invalidated, considering other parts severable and workable is consistent with section 5 of the Tobacco Control Act and Congressional intent. Some comments specifically recommend that should a court invalidate any portion or block the images, the remaining portions should go into effect, as they would promote greater public understanding of the negative health consequences of cigarette smoking. Some comments suggest that severability is appropriate, but FDA should further explain its rationale to ensure judicial consideration of severability, if necessary, to prevent vacation of the entire rule should a court find any portion objectionable. One comment addresses the various scenarios FDA set out in the proposed rule with suggestions of how FDA should proceed in each case. That comment suggests that, if a court blocks the images, FDA should proceed with implementing the textual warning statements and, even if the size of the warnings is reduced, FDA should prioritize maintaining the warning at the top of the pack because of the importance of visibility of the warning.

(Response 102) FDA agrees with comments asserting that, if a portion of this rule is invalidated, severability would be appropriate. Case law supports that conclusion, including case law regarding the severability of statutory provisions. The Supreme Court in *Alaska Airlines, Inc.* v. *Brock,* 480 U.S. 678 (1987), set forth the test for severability of statutory provisions, emphasizing that ''a court should refrain from invalidating more of the statute than is necessary.'' *Id.* at 684 (brackets omitted). There are two prongs to the examination. First, a court should evaluate whether ''the Legislature would [] have enacted those provisions which are within its power, independently of that which is not,'' *i.e.,* ''whether the statute will function in a *manner* consistent with the intent of Congress'' if it is stripped of its unconstitutional provisions. *Id.* at 684, 685. Then, the reviewing court will consider whether ''what is left is fully operative as a law,'' or if instead ''the balance of the legislation is incapable of functioning independently.'' *Id.* at 684 (quotation marks omitted).

The same test is used to determine whether the invalid portion of a statute or the invalid portion of a regulation may be severed from the rest. *See United States* v. *Smith,* 945 F.3d 729, 738 (2d Cir. 2019) (citing decisions addressing statutory severability for the standard to determine regulatory severability). ''Whether the offending portion of a regulation is severable depends upon the intent of the agency *and* upon whether the remainder of the regulation could function sensibly without the stricken provision.'' *MD/DC/DE Broadcasters Ass'n* v. *F.C.C.,* 236 F.3d 13, 22 (D.C. Cir. 2001). *See also K-Mart Corp.* v. *Cartier,* 486 U.S. 281, 294 (1988) (severing a portion of a Customs Service regulation as being in conflict with the statute).

As noted, FDA intends for every portion of this rule to be severable and has concluded that, if some but not all portions of the rule were invalidated, remaining portions could and should function sensibly on their own. FDA's conclusion is informed by Congress's express intent. FDA agrees with the comments that section 5 of the Tobacco Control Act, entitled ''Severability,'' expressly signals Congress's intent for regulations issued under the statute to be severable and for any remaining portion to be legally enforceable should any portion be found invalid. Section 5 provides in relevant part that ''[i]f any . . . of the regulations promulgated under this division . . . is held to be invalid, the remainder . . . shall not be affected and shall continue to be enforced to the fullest extent possible.'' The inclusion of section 5 in the Tobacco Control Act creates a presumption that Congress intended for any invalid portion of a regulation issued under the statute to be severable from the remainder. *Alaska Airlines,* 480 U.S. at 686 (same, for statutes; holding that when Congress explicitly provides for severance by including a severability clause in a statute, there is ''a presumption that Congress did not intend the validity of the statute in question to depend on the validity of the constitutionally offensive provision''). Here, taking into consideration this statutory provision and Congress's stated goals in requiring these warnings, FDA is explicitly stating its intent that the portions of this regulation be interpreted as severable. Therefore, the courts can say without any doubt, and all the more strongly ''without any substantial doubt[,] that the agency would have adopted the severed portion on its own.'' *Am. Petroleum Inst.* v. *Envtl. Prot. Agency,* 862 F.3d 50, 71 (D.C. Cir. 2017) (quotation marks omitted), *modified on other grounds,* 883 F.3d 918 (D.C. Cir. 2018).

The second prong of a severability analysis is whether the remaining portions of a statute or regulation remain workable on their own. In this case, they do. The different text-and-image pairings and the different textual warning statements can be and are intended to be incorporated into the label of a package or an advertisement on an individual basis and therefore ''operate entirely independently of one another.'' *Davis Cty. Solid Waste Mgmt.* v. *U.S. E.P.A.,* 108 F.3d 1454, 1459 (D.C. Cir. 1997) (internal citation omitted). Because the Agency intends as many of the warnings to go forward as possible, and because the regulation will function even if some of the text-and-image pairings or the images are invalidated, any provisions of this rule that may be invalidated are properly severable.

With respect to the comment asserting that FDA lacks the discretion to implement the warning requirements with textual warning statements only or with other deviations from the statutory mandate, FDA notes that the question of severability is distinct from that of the Congressional directive to issue a warning regulation in the first instance. The situation that is the subject of this ''Severability'' section—*i.e.,* the circumstance where a court has disagreed with FDA's conclusions as to the legality of some but not all provisions of the rule—raises different questions from those addressed in the comment. Contrary to what the comment states, FDA is not asserting, and does not need to assert, that it has the authority to promulgate a rule under section 15 U.S.C. 1333 that deviates from the requirements of section 1333. Instead, FDA here is asserting, and need only assert, that in the event that a court invalidates certain provisions of this rule but not others, FDA intends the

remaining provisions to go into effect on their own.

To the extent that the comment questions FDA's authority to oversee implementation of text-only warnings in the event of a court decision invalidating the images but upholding the rest of the rule, FDA disagrees. The comment asserts that, because the Tobacco Control Act directs FDA to issue color graphics to accompany the textual warning statements, FDA is without authority to implement the remaining portions of a rule if a court invalidates the color graphics but not the textual statements. FDA disagrees with any interpretation of the statute that would compel this result. Again, the question here relates only to severability and to what details of the regulation are preserved in the case where some provisions do not survive. The statute provides that FDA ''shall issue regulations that require color graphics depicting the negative health consequences of smoking to accompany the label statements specified in subsection (a)(1)'' (section 201(a) of the Tobacco Control Act). But this language does not dictate that, if some of the text-and-image pairings, images, or textual warning statements were invalidated by a court while other pairings, images, or statements were not invalidated, the result would be to invalidate all of the rule's requirements. For the reasons described above, in the event that some provisions of this rule are invalidated, the statute compels, FDA intends, and courts should recognize as workable the preservation of all remaining portions.

FDA disagrees with comments that suggest that stating its intentions for severability fails to provide the public with adequate notice of the portions of the rule that would take effect if any others are severed and prevents meaningful public comment. The public has had the opportunity to comment on the entire proposal, as well as each required textual warning statement and each required text-and-image pairing, and thus all portions that may take effect if other portions are severed.

FDA also disagrees with comments suggesting that, if, for example, a court struck down any or all of the images but upheld the textual warning statements, the remaining unsevered portions of the rule would not be consistent with the intent of Congress. While it is clear that in section 201 of the Tobacco Control Act Congress intended for color graphics to accompany textual warning statements, and while the affirmative proposal of a regulation by FDA under section 201 requiring only textual warnings would not effectuate that specific intent, this analysis does not answer the question of severability, *i.e.,* of what provisions of a regulation should survive in the event that a court strikes down some but not all provisions of this rulemaking replacing the Surgeon General's warnings with new text-and-image pairings. Here, Congress's intent surely supports preservation. It was clearly the intent of Congress by passing the Tobacco Control Act to replace the stale 1984 Surgeon General's warnings and to increase the size and update the placement of new required cigarette warnings, as well as to require color graphics. In the event that a court determines that a rule is valid with respect to the new textual warning statements but is not valid with respect to other aspects, including the color graphics, implementation of those other aspects would be consistent with Congress's intent to strengthen cigarette warnings.

Likewise, FDA disagrees with comments that it would be unworkable for warnings containing only textual warning statements or only text-and-image pairings that were not invalidated to take effect. FDA is aware of no technical, practical, or other impediment to implementation of individual provisions of this rule without the others. Thus, in the context of the question of severability, FDA concludes that the implementation of warnings containing only textual warning statements would be workable (*i.e.,* if all of the images are struck down), as would the implementation of a smaller number of required warnings (*i.e.,* if some of the text-and-image pairings were found to be invalid and were severed, leaving fewer total pairings or a mixture of warnings that included both text-only and text-and-image pairings). FDA notes that comments do not provide details about why or how the implementation of portions of the regulation would not be workable. However, if companies have specific questions, FDA is ready to work with them regarding implementation issues.

XIII. Economic Analysis of Impacts

We have examined the impacts of the final rule under Executive Order (E.O.) 12866, E.O. 13563, E.O. 13771, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). E.O.s 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). E.O. 13771 requires that the costs associated with significant new regulations ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' We believe that this final rule is an economically significant regulatory action as defined by E.O. 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. We estimate that for a small manufacturer or importer who would be affected by this final rule, initial costs could represent between 2.3 and 42 percent of their annual receipts and recurring costs could represent from 0.1 to 2.7 percent of their annual receipts. Hence, we find that the final rule will have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $154 million, using the most current (2018) Implicit Price Deflator for the Gross Domestic Product. This final rule will result in an expenditure in any year that meets or exceeds this amount.

This final rule requires that one of 11 new cigarette health warnings, each comprising a textual warning statement paired with an accompanying color graphic, in the form of a photorealistic image, appear on cigarette packages and in cigarette advertisements. The final rule further requires that, for cigarette packages, the required warnings be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed throughout the United States in accordance with a plan approved by FDA. The final rule also requires that, for cigarette advertisements, the required warnings must be rotated quarterly in alternating sequence in advertisements for each brand of cigarettes in accordance with a plan approved by FDA.

Pictorial cigarette health warnings promote greater public understanding about the negative health consequences of smoking as they increase the noticeability of the warning's message,

increase knowledge and learning about the negative health consequences of smoking, and benefit diverse populations that have disparities in knowledge about the negative health consequences of smoking. We do not predict the size of these benefits at this time. We discuss the informational effects qualitatively.

The costs of this final rule consist of initial and recurring labeling costs associated with changing cigarette labels to accommodate the new cigarette health warnings, design and operation costs associated with the random and equal display and distribution of the required warnings for cigarette packages and quarterly rotations of the required warnings for cigarette advertisements, advertising-related costs, and costs associated with government administration and enforcement of the rule. Using a 20-year time horizon, we estimate that the present value of the costs of this final rule ranges from $1.5 billion to $1.7 billion, with a mean estimate of $1.6 billion, using a three percent discount rate, and ranges from $1.1 billion to $1.3 billion, with a mean estimate of $1.2 billion, using a seven percent discount rate (2018$). Annualized costs, which are presented below in Table 1, range from $100 million per year to $114 million per year, with a mean estimate of $107 million per year, using a three percent discount rate, and range from $107 million per year to $122 million per year, with a mean estimate of $114 million per year, using a seven percent discount rate (2018$).

Because it is not possible to compare benefits and costs directly when the benefits are not quantified, we employ a break-even approach. If the information provided by the cigarette health warning on each cigarette package were valued at about $0.01 (for every pack sold annually nationwide), then the benefits that would be generated by the final rule would equal or exceed the estimated annual costs.

TABLE 1—SUMMARY OF THE INFORMATIONAL EFFECTS AND COSTS OF THE FINAL RULE

[In millions of 2018$]

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Informational Effects	Pictorial cigarette health warnings promote greater public understanding about the negative health consequences of smoking as they increase the noticeability of the warning's message, increase knowledge and learning of the negative health consequences of smoking, and help reduce disparities in knowledge about the negative health consequences of smoking across diverse populations. If the information provided by the cigarette health warning on each cigarette package was valued at about $0.01 (for every pack sold annually nationwide), then the benefits that would be generated by the final rule would equal or exceed the estimated annual costs.						
Costs:							
Annualized Monetized $millions/year.	$114.4	$106.6	$122.2	2018	7	20	Effective date of 15 months from date of publication of final rule.
	106.7	100.0	113.5	2018	3	20	

In line with E.O. 13771, in Table 2 we estimate present and annualized values of costs and cost savings over an infinite time horizon. With a seven percent discount rate, discounted relative to year 2016, the estimated annualized net costs equal $73 million in 2016 dollars over an infinite horizon. Based on these costs, this final rule is considered a regulatory action under E.O. 13771.

TABLE 2—E.O. 13771 SUMMARY TABLE

[In millions of 2016$, over an infinite time horizon]

Item	Primary estimate (7%)
Present Value of Costs	$1,046.0
Present Value of Cost Savings	0.0
Present Value of Net Costs	1,046.0
Annualized Costs	73.2
Annualized Cost Savings	0.0
Annualized Net Costs	73.2

Note: Effective date is 15 months from date of publication of final rule.

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. The full analysis of economic impacts is available in the docket for this final rule (Ref. 16) and at *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

XIV. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Additionally, the action is not anticipated to pose serious harm to the environment and to adversely affect a species or the critical habitat of a species as stipulated under 21 CFR 25.21(b). Therefore, neither an environmental assessment nor an environmental impact statement is required.

XV. Paperwork Reduction Act of 1995

The final rule contains information collection requirements that are subject

to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521) (PRA). The title, description, and respondent description of the information collection provisions are shown in the following paragraphs with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Required Warnings for Cigarette Packages and Advertisements.

Description: The requirement for submission of plans for cigarette packages and advertisements, and the specific marketing requirements relating to the random and equal display and distribution of required warnings on cigarette packaging and quarterly rotation of required warnings in alternating sequence in cigarette product advertising, appear in § 1141.10(g). A record of the FDA-approved plan must also be established and maintained.

Description of Respondents: The respondents to this collection of information are manufacturers, distributors, and certain retailers of cigarettes who will be required to submit plans for cigarette packages and advertisements to FDA.

As required by section 3506(c)(2)(B) of the PRA, FDA provided an opportunity for public comment on the information collection requirements of the proposed rule that published in the **Federal Register** of August 16, 2019 (84 FR 42754). No PRA-related comments were received.

FDA requests that each cigarette plan cover both packaging and advertising as applicable. The tobacco product manufacturer, distributor, or retailer should demonstrate how they plan to achieve the random display in each 12-month period, in as equal a number of times as is possible on each brand of the product, and random distribution in all areas of the United States of the required warnings on packages and the quarterly rotation in advertisements. Required warnings for cigarettes must be randomly displayed, in as equal a number of times as is possible, and randomly distributed on packages, and rotated quarterly in advertisements, in accordance with an FDA-approved plan.

FDA strongly encourages entities to submit their cigarette plans as soon as possible after publication of this final rule, and in any event within 5 months after publication of this final rule. Packages and advertisements of cigarettes are required to bear the required warnings beginning 15 months after the date of publication of the final rule. FDA intends to request an amendment to a plan under review if FDA needs clarification of information in the plan or other additional information to determine whether it could approve the plan. Any such amendments would likely increase the overall review time.

After FDA approval of an initial plan, a supplement to the approved plan should be submitted to FDA and approved before making changes to the random and equal display or distribution of required warnings on packages or the quarterly rotation of required warnings in advertisements. For a new brand, a new plan or a supplement to an FDA-approved plan is required to be submitted and approved before distributing packages and advertisements for that new brand.

However, in lieu of a supplement to an FDA-approved plan for a new brand, manufacturers may reference in their initial plan all brands in their product listing(s) under section 905(i) of the FD&C Act and incorporate any new brands into their approved plan, so long as no other changes are made to the plan. For retailer-generated advertising, retailers may list ''all brands'' in their plan, which would cover future brands, so long as the plan provides for the same schedule for quarterly rotation of the required warnings for all brands.

FDA allows electronic submissions, via FDA's Electronic Submissions Gateway, and written submissions. FDA strongly encourages electronic submission to facilitate efficiency and timeliness of submission and processing.

For each brand of cigarettes, the plan for packaging should explain how: Each of the required warnings will be randomly displayed during each 12-month period on each brand; each of the required warnings will be displayed in as equal a number of times as possible on each brand of the product; and product packages will be randomly and equally distributed in all areas of the United States in which the product is marketed. FDA expects that a plan for random and equal display and distribution of required warnings on packages will ordinarily be based on the date of manufacture or shipment of the product. For each cigarette brand, the plan for advertising should explain how the required warnings will be rotated quarterly in advertisements and how the quarterly rotations will occur in alternating sequence. Among other things, the plan should specify the initial rotation timeframe on which quarterly rotation is based and, if the rotation timeframe varies for different types/forms of advertising, specify the different quarterly timeframes associated with the different types/forms of advertising, and describe the quarterly schedule for rotating each of the required warnings for each cigarette brand. FDA would not consider a plan that merely restated the regulatory requirements to be sufficiently detailed to enable FDA to approve the plan.

FDA's review of a plan would only be for determining compliance with the regulatory criteria for approval of a plan, as set forth in § 1141.10(g)(1) and (2). FDA requests that plans submitted for review include representative samples of packages and advertisements with each of the required warnings. Such samples would place the plan in context and, therefore, facilitate FDA's review of the plan, not a review of the content of the package labels and advertisements. Approval of a plan does not represent a determination by FDA that any package or advertisement complies with any of the other requirements regarding the placement, font type, size, and color of the warnings found in section 4 of the FCLAA and part 1141, or any other requirements under the FD&C Act and its implementing regulations.

FDA intends to communicate the approval of a plan with a letter to the submitter. After FDA approval of an initial plan, a supplement to the approved plan would need to be submitted to FDA for review and approved before making changes to the display or distribution of required warnings on packages or the rotation of required warnings in advertisements. For a new brand, a new plan or a supplement to an approved plan would need to be submitted and approved before displaying or distributing packages and advertisements for that new brand.

However, in lieu of a supplement to an approved plan for a new brand, manufacturers may reference in their initial plan ''all brands'' in their product listing(s) under section 905(i) of the FD&C Act and incorporate any new brands into their approved plan, so long as no other changes are made to the plan. For retailer-generated advertising, retailers may list ''all brands'' in their plan, which would cover future brands, so long as the plan provides for the same schedule for quarterly rotation of the required warnings for all brands.

TABLE 3—ESTIMATED ONE-TIME REPORTING BURDEN [1]

Type of plan	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Initial Plans	59	1	59	150	8,850
Supplements	30	1	30	75	2,250
Total					11,100

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden estimates are based on FDA's experience with information collections for other tobacco product plans (*i.e.,* OMB control numbers 0910–0671 (smokeless tobacco products) and 0910–0768 (cigars)) and 2017 Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB) data.

As discussed in the Final Regulatory Impact Analysis (see section XIII; Ref. 16), based on 2017 TTB data, FDA estimates 59 entities will be affected by the rule. We estimate these 59 entities will submit a one-time initial plan, and it will take an average of 150 hours per respondent to prepare and submit a plan for packaging and advertising for a total of 8,850 hours. We estimate that about half of respondents will submit a supplement. If a supplement to an approved plan is submitted, FDA estimates it will take half the time per response. We estimate receiving 30 supplements at 75 hours per response for a total of 2,250 hours. FDA estimates that the total hours for submitting initial plans and supplements will be 11,100.

Section 1141.10(g)(4) would establish that each tobacco product manufacturer required to randomly and equally display and distribute required warnings on packaging or quarterly rotate required warnings in advertisements in accordance with an FDA-approved plan under section 4 of the FCLAA and this part must maintain a copy of the FDA-approved plan (approved under § 1141.10(g)(3)). This copy (or record) of such FDA-approved plan must be available for inspection and copying by officers or employees of FDA. This subsection would require that the record(s) be retained while in effect and for a period of not less than 4 years from the date of FDA's approval of the plan.

TABLE 4—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Plan records	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Records	59	1.5	89	3	267
Total					267

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates that 59 recordkeepers will keep a total of about 89 records at 3 hours per record for a total of 267 hours. As stated previously, these estimates are based on FDA's experience with information collections for other tobacco product plans (*i.e.,* OMB control numbers 0910–0671 and 0910–0768). Based on our estimates for the submission of initial plans and supplements (that all respondents will submit initial plans and about half of respondents will submit supplements), we estimate that each recordkeeper will keep an average of 1.5 records.

FDA estimates that the total burden for this information collection is 11,367 hours (11,100 reporting hours + 267 recordkeeping hours).

FDA believes that the required warnings for cigarette packages and cigarette advertisements in § 1141.10 are not subject to review by OMB under the PRA because they do not constitute a ''collection of information'' under that statute (44 U.S.C. 3501–3521). Rather, these labeling statements are a ''public disclosure'' of information originally supplied by the Federal Government to the recipient for the purpose of ''disclosure to the public'' (5 CFR 1320.3(c)(2)).

The information collection provisions in the final rule have been submitted to OMB for review as required by section 3507(d) of the PRA.

Before the effective date of the final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in the final rule. 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.

XVI. Federalism

We have analyzed the final rule in accordance with the principles set forth in E.O. 13132. We have determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the E.O. and, consequently, a federalism summary impact statement is not required.

XVII. Consultation and Coordination With Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that have substantial direct effects 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. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive Order and, consequently, a tribal summary impact statement is not required. We received two comments related to tribal consultation and we respond to those comments in the following paragraphs.

(Comment 103) One comment objects to the rulemaking as a product of a court order rather than of deliberatively reasoned decision making, suggesting that due to the expedited schedule and lack of meaningful tribal consultation, the effectiveness of the rule in promoting public health and its disproportionate effect on tribal communities has not been fully considered. The comment notes that, because the tribe relies in part on tobacco revenues to fund basic governmental services, the rule threatens to have an outsized effect on tribal manufacturers and requests that meaningful tribal consultation occur prior to finalizing the rule to discuss the impact and cost incurred by tribal governments.

(Response 103) FDA agrees that collaboration and consultation with federally recognized tribal governments, per the FDA Tribal Consultation Policy and E.O. 13175, is important. FDA engages with tribal stakeholders, including tribal government leaders, tribal health leaders, and public health professionals, about the implementation and enforcement of the Tobacco Control Act and related regulations by various methods (*e.g.,* ''Dear Tribal Leader'' letters, All Tribes' Calls, formal and informal consultations as well as face-to-face meetings). We also encourage tribes to stay informed about developments related to tobacco products through our website (*https://www.fda.gov/TobaccoProducts*).

We disagree that the tribal consultation for the proposed rule was inadequate. There were several opportunities for tribes to engage with FDA about the proposed rule, including the impact and costs of the proposed rule on tribal manufacturers, which was considered as part of the Preliminary Regulatory Impact Analysis (*https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm*). In a ''Dear Tribal Leader'' letter dated August 15, 2019, FDA initiated consultation with federally recognized Indian tribes on the proposed rule and invited tribes to participate in an All Tribes' Call on September 19, 2019. The purpose of the call was to provide an overview of the proposed rule, answer questions, and hear tribal comments on the proposed rule. We provided contact information in the letter and during the call to help ensure that there was a mechanism to address any further questions. We also encouraged tribes to submit written comments on the proposed rule and supporting documents such as the Preliminary Regulatory Impact Analysis.

(Comment 104) One comment supports the rule as a means to increase understanding of the negative health consequences of smoking and encourages FDA to ensure that these efforts reach American Indian/Alaska Native populations, which have the highest rates of cigarette smoking (Ref. 26) but lack understanding of the scope of the negative health consequences of smoking. The comment suggests that FDA partner with Urban Indian Health organizations to achieve the goals of this and any future goals, not as a substitute for tribal consultation but as a means to reach a target population.

(Response 104) We agree that the rule will promote greater public understanding of the negative health consequences of smoking. We note that in addition to this important rulemaking, FDA is developing other outreach with American Indian/Alaska Native partners.

XVIII. References

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

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List of Subjects in 21 CFR Part 1141

Advertising, Incorporation by reference, Labeling, Packaging and containers, Tobacco, Smoking.

■ Therefore, under the Federal Cigarette Labeling and Advertising Act, the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 1141 is revised to read as follows:

PART 1141—REQUIRED WARNINGS FOR CIGARETTE PACKAGES AND ADVERTISEMENTS

Subpart A—General Provisions

Sec.
1141.1 Scope.
1141.3 Definitions.
1141.5 Incorporation by reference.

Subpart B—Required Warnings for Cigarette Packages and Advertisements

1141.10 Required warnings.
1141.12 Misbranding of cigarettes.

Authority: 15 U.S.C. 1333; 21 U.S.C. 371, 374, 387c, 387e, 387i; Secs. 201 and 202, Pub. L. 111–31, 123 Stat. 1776.

Subpart A—General Provisions

§ 1141.1 Scope.

(a) This part sets forth the requirements for the display of required warnings on cigarette packages and in advertisements for cigarettes.

(b) The requirements of this part do not apply to manufacturers or distributors of cigarettes that do not manufacture, package, or import cigarettes for sale or distribution within the United States.

(c) A cigarette retailer will not be in violation of § 1141.10 for packaging that:

(1) Contains a warning;

(2) Is supplied to the retailer by a license- or permit-holding tobacco product manufacturer, or distributor; and

(3) Is not altered by the retailer in a way that is material to the requirements of section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) or this part.

(d) Section 1141.10(d) applies to a cigarette retailer only if that retailer is responsible for or directs the warnings required under § 1141.10 for advertising. However, this paragraph (d) does not relieve a retailer of liability if the retailer displays, in a location open to the public, an advertisement that does not contain a warning or has been altered by the retailer in a way that is material to the requirements of section 4 of the Federal Cigarette Labeling and Advertising Act or this part.

§ 1141.3 Definitions.

For purposes of this part:

Cigarette means—

(1) Any roll of tobacco wrapped in paper or in any substance not containing tobacco; and

(2) Any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in paragraph (1) of this definition.

Commerce means:

(1) Commerce between any State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island and any place outside thereof;

(2) Commerce between points in any State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island, but through any place outside thereof; or

(3) Commerce wholly within the District of Columbia, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Island, Kingman Reef, or Johnston Island.

Distributor means any person who furthers the distribution of cigarettes, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption. Common carriers are not considered distributors for the purposes of this part.

Front panel and *rear panel* mean the two largest sides or surfaces of the package.

Manufacturer means any person, including any repacker or relabeler, who manufactures, fabricates, assembles, processes, or labels a finished cigarette product; or imports any cigarette that is intended for sale or distribution to consumers in the United States.

Package or *packaging* means a pack, box, carton, or container of any kind in which cigarettes are offered for sale, sold, or otherwise distributed to consumers.

Person means an individual, partnership, corporation, or any other business or legal entity.

Retailer means any person who sells cigarettes to individuals for personal consumption, or who operates a facility where vending machines or self-service displays of cigarettes are permitted.

United States, when used in a geographical sense, includes the several States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, and Johnston Island. The term ''State'' includes any political division of any State.

§ 1141.5 Incorporation by reference.

(a) Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at U.S. Food and Drug Administration, Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and is available from the source listed in paragraph (b) of this section. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fedreg.legal@nara.gov* or go to *www.archives.gov/federal-register/cfr/ibr-locations.html.*

(b) Center for Tobacco Products, U.S. Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993; 1–888–463–6332. You may also obtain the material at *https://www.fda.gov/cigarette-warning-files.*

(1) ''Required Cigarette Health Warnings, 2020'', IBR approved for § 1141.10.

(2) [Reserved]

Subpart B—Required Warnings for Cigarette Packages and Advertisements

§ 1141.10 Required warnings.

(a) *Required warnings.* A required warning must include the following:

(1) One of the following textual warning label statements:

(i) WARNING: Tobacco smoke can harm your children.

(ii) WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.

(iii) WARNING: Smoking causes type 2 diabetes, which raises blood sugar.

(iv) WARNING: Smoking reduces blood flow to the limbs, which can require amputation.

(v) WARNING: Smoking causes cataracts, which can lead to blindness.

(vi) WARNING: Smoking causes bladder cancer, which can lead to bloody urine.

(vii) WARNING: Smoking reduces blood flow, which can cause erectile dysfunction.

(viii) WARNING: Smoking causes head and neck cancer.

(ix) WARNING: Smoking can cause heart disease and strokes by clogging arteries.

(x) WARNING: Smoking during pregnancy stunts fetal growth.

(xi) WARNING: Smoking causes COPD, a lung disease that can be fatal.

(2) A color graphic to accompany the textual warning label statement.

(b) *Accurately reproduced.* Each required warning, comprising a combination of a textual warning label statement and its accompanying color graphic, must be accurately reproduced as shown in the materials contained in ''Required Cigarette Health Warnings, 2020,'' which is incorporated by reference at § 1141.5.

(c) *Packages.* It is unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any cigarettes unless the package of which bears a required warning in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act and this part.

(1) The required warning must appear directly on the package and must be clearly visible underneath any cellophane or other clear wrapping.

(2) The required warning must comprise at least the top 50 percent of the front and rear panels; provided, however, that on cigarette cartons, the required warning must be located on the left side of the front and rear panels of the carton and must comprise at least the left 50 percent of these panels.

(3) The required warning must be positioned such that the text of the required warning and the other information on that panel of the package have the same orientation.

(d) *Advertisements.* It is unlawful for any manufacturer, distributor, or retailer of cigarettes to advertise or cause to be advertised within the United States any cigarette unless each advertisement bears a required warning in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act and this part.

(1) For print advertisements and other advertisements with a visual component (including, for example, advertisements on signs, retail displays, internet web pages, digital platforms, mobile applications, and email correspondence), the required warning must appear directly on the advertisement.

(2) The required warning must comprise at least 20 percent of the area of the advertisement in a conspicuous and prominent format and location at the top of each advertisement within the trim area, if any.

(3) The text in each required warning must be in the English language, except as follows:

(i) In the case of an advertisement that appears in a non-English medium, the text in the required warning must appear in the predominant language of the medium whether or not the advertisement is in English; and

(ii) In the case of an advertisement that appears in an English language medium but that is not in English, the text in the required warning must appear in the same language as that principally used in the advertisement.

(4) For English-language and Spanish-language warnings, each required warning must be accurately reproduced as shown in the materials contained in ''Required Cigarette Health Warnings, 2020,'' which is incorporated by reference at § 1141.5.

(5) For non-English-language warnings, other than Spanish-language warnings, each required warning must be accurately reproduced as shown in the materials contained in ''Required Cigarette Health Warnings, 2020,'' which is incorporated by reference at § 1141.5, including the substitution and insertion of a true and accurate translation of the textual warning label statement in place of the English language version. The inserted textual warning label statement must comply with the requirements of section 4 of the Federal Cigarette Labeling and Advertising Act, including area and other formatting requirements, and this part.

(e) *Irremovable or permanent warnings.* The required warnings must be indelibly printed on or permanently affixed to the package or advertisement. These warnings, for example, must not be printed or placed on a label affixed to a clear outer wrapper that is likely to be removed to access the product within the package.

(f) *Sale or distribution.* No person may manufacture, package, sell, offer for sale, distribute, or import for sale or distribution within the United States cigarettes whose packages or advertisements are not in compliance with section 4 of the Federal Cigarette Labeling and Advertising Act and this part, except as provided by § 1141.1(c) and (d).

(g) *Marketing requirements*—(1) *Random display.* The required warnings for packages specified in paragraph (a) of this section must be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which the product is marketed in accordance with a plan submitted by the tobacco product manufacturer, distributor, or retailer to, and approved by, the Food and Drug Administration.

(2) *Rotation.* The required warnings for advertisements specified in paragraph (a) of this section must be rotated quarterly in alternating sequence in advertisements for each brand of cigarettes in accordance with a plan submitted by the tobacco product manufacturer, distributer, retailer to, and approved by, the Food and Drug Administration.

(3) *Review.* The Food and Drug Administration will review each plan submitted under this section and approve it if the plan:

(i) Will provide for the equal distribution and display on packaging and the rotation required in advertising under this subsection; and

(ii) Assures that all of the labels required under this section will be displayed by the tobacco product manufacturer, distributor, or retailer at the same time.

(4) *Record retention.* Each tobacco product manufacturer required to randomly and equally display and distribute warnings on packaging or rotate warnings in advertisements in accordance with an FDA-approved plan under section 4 of the Federal Cigarette Labeling and Advertising Act and this part must maintain a copy of such FDA-approved plan and make it available for inspection and copying by officers or employees duly designated by the Secretary of Health and Human Services. The FDA-approved plan must be retained while in effect and for a period of not less than 4 years from the date it was last in effect.

§ 1141.12 Misbranding of cigarettes.

(a) A cigarette will be deemed to be misbranded under section 903(a)(1) of the Federal Food, Drug, and Cosmetic Act if its package does not bear one of the required warnings in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act and this part. A cigarette will be deemed to be misbranded under section 903(a)(7)(A) of the Federal Food, Drug, and Cosmetic Act if its advertising does not bear one of the required warnings in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act and this part.

(b) A cigarette advertisement and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor will be deemed to include a brief statement of relevant warnings for the purposes of section 903(a)(8) of the Federal Food, Drug, and Cosmetic Act if it bears one of the required warnings in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act and this part. A cigarette distributed or offered for sale in any State shall be deemed to be misbranded under section 903(a)(8)

of the Federal Food, Drug, and Cosmetic Act unless the manufacturer, packer, or distributor includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to the cigarette one of the required warnings in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act and this part.

Dated: March 10, 2020.

Stephen M. Hahn,

Commissioner of Food and Drugs.

[FR Doc. 2020–05223 Filed 3–17–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1141

[Docket No. FDA–2020–D–0988]

Required Warnings for Cigarette Packages and Advertisements: Small Entity Compliance Guide; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a final guidance for industry entitled ''Required Warnings for Cigarette Packages and Advertisements: Small Entity Compliance Guide.'' This guidance is intended to help small businesses understand and comply with FDA's document entitled ''Tobacco Products: Required Warnings for Cigarette Packages and Advertisements,'' which establishes new required cigarette health warnings for cigarette packages and advertisements.

DATES: March 18, 2020.

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–2020–D–0988 for ''Required Warnings for Cigarette Packages and Advertisements: Small Entity Compliance Guide.'' 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.

• 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.

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 Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Lauren Belcher or Annette Marthaler, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002, 1–877–287–1373, email: *CTPRegulations@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled ''Required Warnings for Cigarette Packages and Advertisements: Small Entity Compliance Guide.'' FDA is issuing this guidance to help small businesses understand and comply with the final rule, codified at 21 CFR part 1141, entitled ''Tobacco Products: Required Warnings for Cigarette Packages and Advertisements'', that establishes new required cigarette health warnings for cigarette packages

and advertisements and is published elsewhere in this edition of the **Federal Register**. The final rule implements a provision of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) that requires FDA to issue regulations requiring color graphics depicting the negative health consequences of smoking to accompany new textual warning label statements. The Tobacco Control Act amends the Federal Cigarette Labeling and Advertising Act (FCLAA) (15 U.S.C. 1333) to require each cigarette package and advertisement to bear one of the new required warnings. Additionally, as required under the FCLAA, the rule establishes marketing requirements that include the random and equal display and distribution of the required warnings on cigarette packages and quarterly rotation of the required warnings in cigarette advertisements. FDA has prepared this Small Entity Compliance Guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104–121).

II. Significance of Guidance

FDA is issuing this guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on assisting small businesses to understand and comply with FDA's final rule, ''Tobacco Products: Required Warnings for Cigarette Packages and Advertisements.'' 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.

III. Paperwork Reduction Act of 1995

This guidance refers to collections of information described in FDA's rule on ''Tobacco Products; Required Warnings for Cigarette Packages and Advertisements,'' which this guidance is intended to interpret. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The information collection provisions in the final rule have been submitted to OMB for review as required by section 3507(d) of the Paperwork Reduction Act of 1995.

IV. Electronic Access

Persons with access to the internet may obtain an electronic version of the guidance at either *https://www.regulations.gov* or *https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm.*

Dated: March 9, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–05211 Filed 3–17–20; 8:45 am]

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