

There are two parts to submitting an application. First, complete the information requested via this electronic form: https://docs.google.com/forms/d/e/1FAIpQLSd4Eh7luDrctPi_ONYslpqoqBnRpHno9mppyKZ_TgZPbYjSGg/viewform?usp=sharing&oid=109592692527580875505. Next, email your CV or resume and a letter of endorsement from your organization or organization's leadership, endorsing you to represent your company, in PDF format to fscac@gsa.gov with the subject line: FSCAC APPLICATION—[Applicant Name]. The letter of endorsement must come from your organization or organization's leadership. If you are the CEO, then it must come from another member of the executive team of your organization, as you cannot endorse yourself. The letter must be signed and specifically state that you are authorized to apply to FSCAC as a representative of your organization.

Applications that do not include the completion of the above instructions will not be considered.

Letters of Recommendation may also be submitted if desired by the applicant; however, please note they may or may not have an impact on final appointments and are not required for an application to be considered.

Stephanie Shutt,

Chief of Staff, Federal Acquisition Service,
General Services Administration.

[FR Doc. 2026-10233 Filed 5-20-26; 8:45 am]

BILLING CODE 6820-34-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC-2026-0892]

Notice of Order Under Sections 362 and 365 of the Public Health Service Act Suspending Introduction of Certain Persons From Countries Where a Communicable Disease Exists

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), a component of the Department of Health and Human Services (HHS), announces the issuance of an Order under Section 362 and 365 of the Public Health Service Act that suspends the introduction of certain persons from countries where an outbreak of a communicable disease exists for a

period of 30 days. The Order was issued on May 18, 2026.

DATES: This action took effect May 18, 2026.

Written comments must be received on or before June 22, 2026.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2026-0892 by either of the methods listed below. Do not submit comments by email. CDC does not accept comments by email.

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Mail:* Division of Global Migration Health, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H16-4, Atlanta, GA 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to <http://regulations.gov>, including any personal information provided. For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Matthew J. Buzzelli, Chief of Staff, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS V18-2, Atlanta, GA 30329. Phone: 404-639-7000. Email: cdceregulations@cdc.gov.

SUPPLEMENTARY INFORMATION: On May 18, 2026, the Senior Official Carrying out the Delegable Duties of the Director of the Centers for Disease Control and Prevention issued the following Order prohibiting the introduction of certain persons who have departed from, or were otherwise present within, specified countries during the last 21 days. The order is effective for a period of 30 days.

A copy of the order is provided below and a copy of the signed order can be found at <https://www.cdc.gov/ebola/situation-summary/index.html>.

U.S. Department of Health and Human Services Centers for Disease Control and Prevention (CDC)

Order Under Sections 362 & 365 of the Public Health Service Act

(42 U.S.C. 265, 268) and 42 CFR 71.40

Order Suspending the Right To Introduce Certain Persons From Countries Where a Quarantinable Communicable Disease Exists

I. Executive Summary

The Centers for Disease Control and Prevention (CDC), a component of the U.S. Department of Health and Human Services (HHS), issues this Order pursuant to Sections 362 and 365 of the Public Health Service (PHS) Act, 42 U.S.C. 265, 268, and their

implementing regulations. This Order suspends the right to introduce “covered aliens,” as defined herein, into the United States for a period of thirty days, subject to the outcome of an ongoing comprehensive public health risk assessment. This Order is necessary to protect the health of the United States from the serious risk posed by the introduction of Ebola disease into the United States by covered aliens based on the emergent outbreak of Ebola disease caused by the Bundibugyo virus strain confirmed present in Democratic Republic of the Congo (DRC) and Uganda.

This suspension Order applies to covered aliens who have departed from, or were otherwise present within, DRC, Uganda, or South Sudan during the last 21 days (regardless of their country of origin). This Order is based on an assessment of the most recently available data and current conditions regarding the Ebola disease outbreak.

This order is time-limited and shall be in effect for 30 days from the date of issuance. This Order is intended to address the serious risk of introduction of Ebola disease into the United States, while allowing the U.S. Government the time necessary to conduct a full assessment of the unique public health risks posed by Ebola disease, assist with implementing surveillance, diagnostic capabilities and contact tracing, and develop a comprehensive mitigation and containment strategy in consultation with other stakeholders.

II. Authority, Scope, and Purpose

I issue this Order pursuant to Sections 362 and 365 of the Public Health Service (PHS) Act, 42 U.S.C. 265, 268, and their implementing regulations under 42 CFR part 71,¹ which authorize the CDC Director to suspend the right to introduce² persons into the United States when the Director determines that the existence of a quarantinable communicable disease in a foreign country or place creates a serious danger of the introduction of such disease into the United States and the danger is so increased by the introduction of persons from the foreign country or place that a temporary suspension of the right of such introduction is necessary to protect public health.

This Order applies to persons who have departed from, or were otherwise present within, Democratic Republic of Congo, Uganda, and South Sudan during the last 21 days (regardless of their country of origin), subject to the exceptions detailed below. For purposes of this Order, I refer to persons covered by the Order as “covered aliens.”

This Order does *not* apply to the following:

¹ Control of Communicable Diseases; Foreign Quarantine: Suspension of the Right to Introduce and Prohibition of Introduction of Persons into United States from Designated Foreign Countries or Places for Public Health Purposes, 85 FR 56424 (Sept. 11, 2020); 42 CFR 71.40.

² *Suspension of the right to introduce* means to cause the temporary cessation of the effect of any law, rule, decree, order, or settlement agreement pursuant to which a person might otherwise have the right to be introduced or seek introduction into the United States. 42 CFR 71.40(b)(5).

- U.S. citizens, U.S. nationals, and lawful permanent residents;³
- Members of the armed forces of the United States and associated personnel, U.S. government personnel serving overseas, associated personnel, and their spouses and children, subject to required assurances;⁴
- Persons whom customs officers determine, with approval from a supervisor, should be excepted from this Order based on the totality of the circumstances, including consideration of significant law enforcement, officer and public safety, humanitarian, and public health interests. The U.S. Department of Homeland Security (DHS) will consult with CDC regarding the standards for such exceptions to help ensure consistency with current CDC guidance and public health recommendations; and
- Noncitizens who would otherwise be subject to this Order, who are permitted to enter the United States as part of a DHS-approved process, where the process approved by DHS has been documented and shared with CDC, and includes appropriate mitigation protocols, per CDC guidance.

The purpose of this order is two-fold. First, this Order aims to immediately minimize the number of covered aliens entering the United States who have been within countries experiencing a known or suspected outbreak of Ebola disease and thereby reduce the risk of introduction of Ebola disease into the United States. Second, this Order is intended to facilitate a thorough assessment and complete understanding of the full public health risk profile associated with the Ebola disease outbreak. Thirty days is the minimum amount of time necessary for CDC to conduct the assessment, which will enable the acting CDC Director to make an informed determination regarding what restrictions are necessary going forward and provide the opportunity for the development of a comprehensive mitigation and containment plan in consultation with other stakeholders.

III. Factual Basis

A. Ebola Disease

Viral hemorrhagic fever refers to a group of severe illnesses caused by certain viruses that damage the body's blood vessels and affect the ability of the blood to clot properly. Viral hemorrhagic fevers include diseases such as Ebola, Marburg, Lassa fever, and dengue hemorrhagic fever.

Ebola virus disease (EVD) is a severe and often fatal illness caused by viruses in the Ebola family. Ebola disease outbreaks occur mainly in parts of sub-Saharan Africa and can spread rapidly in communities with limited healthcare resources. Ebola disease caused by the Bundibugyo virus is a rare form of Ebola first identified during an outbreak in Bundibugyo District, Uganda, in 2007. Bundibugyo virus is one of several species within the orthoebolavirus family and causes symptoms similar to other forms of Ebola, including fever, weakness, vomiting, diarrhea, and, in severe cases, hemorrhagic complications and organ failure. The disease spreads through direct contact

with infected bodily fluids or contaminated materials.

The incubation period for Ebola virus disease caused by the Bundibugyo virus is typically between 2 and 21 days, with most people developing symptoms within 4 to 10 days after exposure. During this incubation period, infected individuals do not spread the virus until symptoms begin.

Screening for Bundibugyo virus disease focuses on identifying symptoms and possible exposure history, such as recent travel to affected areas or contact with infected individuals. Suspected patients are evaluated for symptoms including fever, weakness, vomiting, diarrhea, and bleeding, and laboratory confirmation is performed using specialized tests such as PCR (polymerase chain reaction) to detect the virus in blood and other body fluid samples. Health authorities also use temperature checks, contact tracing, and isolation procedures to prevent transmission.

There are currently no widely approved vaccines or specific antiviral treatments for the Bundibugyo strain of Ebola disease. Treatment mainly consists of supportive care, including intravenous fluids, electrolyte replacement, oxygen support, pain and fever management, and treatment of secondary infections. Early medical care significantly improves survival chances. Robust public health measures such as early detection, rapid isolation, strong infection prevention measures (*i.e.*, use of personal protective equipment (PPE)), and monitoring of contacts are critical to controlling outbreaks and reducing deaths.

B. Ongoing Bundibugyo Virus Disease Outbreak

Presently, there is a confirmed ongoing outbreak of Ebola disease caused by the Bundibugyo virus in DRC and Uganda. The current outbreak is centered in eastern DRC's Ituri Province, where hundreds of suspected cases and dozens of deaths have been reported. Conflict, weak health infrastructure, and relatively porous borders in the region are complicating containment efforts.

Uganda has confirmed imported cases linked to travel from DRC, including one case detected in Kampala, imported from a traveler from DRC. Ugandan authorities have activated emergency response systems, expanded surveillance, and strengthened screening at borders and health facilities. Uganda has significant prior experience managing Ebola disease outbreaks, including the Sudan virus strain outbreak in 2025, which improved preparedness and response capacity.

South Sudan has not reported confirmed cases in the current outbreak, but it is considered at high risk because of its close border with affected areas in eastern DRC and Uganda, limited healthcare infrastructure, and cross-border population movement. Regional and international agencies, including WHO and Africa CDC, are supporting preparedness measures, surveillance, and coordination among the three countries to prevent wider spread. Despite these efforts there is a risk that the outbreak could spread beyond these three

countries, and ultimately reach the United States, through international travel by infected individuals during the virus's incubation period, when they have been exposed but are not yet showing symptoms. Travelers moving between affected countries and major international transit hubs could unknowingly carry the virus before becoming ill.

DRC, Uganda, and South Sudan are connected to the global aviation network through a series of regional and international transit hubs that provide pathways into the United States. Travelers departing from outbreak-affected regions frequently transit through densely populated metropolitan airports such as Addis Ababa Bole International Airport (ADD), Jomo Kenyatta International Airport (NBO) in Nairobi, Hamad International Airport (DOH) in Doha, Dubai International Airport (DXB), and Istanbul Airport (IST), all of which maintain extensive passenger connectivity to major U.S. gateway airports including John F. Kennedy International Airport (JFK), Washington Dulles International Airport (IAD), Hartsfield-Jackson Atlanta International Airport (ATL), Chicago O'Hare International Airport (ORD), and Los Angeles International Airport (LAX). These international transportation corridors support continuous movement of travelers between Central and East Africa and major U.S. metropolitan centers, increasing the likelihood that individuals exposed to Ebola virus disease could enter the United States before symptoms become apparent. Complex multi-leg itineraries and the rapid pace of international travel create substantial challenges for identifying potentially infected travelers before arrival.

The risk of Bundibugyo virus disease introduction into the United States is heightened by the virus's incubation period, which can extend up to 21 days, allowing infected individuals to travel internationally while asymptomatic and therefore unlikely to be detected through routine symptom-based screening measures. A traveler infected in outbreak regions of DRC and Uganda may transit through multiple countries and major international airports before developing fever or other clinical signs of disease. Upon arrival in major U.S. metropolitan areas, travelers who become symptomatic could interact with crowded airport environments, domestic transportation systems, healthcare facilities, hotels, or community settings prior to diagnosis and isolation. Because modern aviation networks enable rapid movement from outbreak zones to the United States within one to two days, even a limited number of infected travelers could create significant public health response demands, particularly if exposure events occur in high-density urban environments. The interconnected nature of global air travel therefore presents a credible pathway for Bundibugyo virus disease importation into the United States, underscoring the importance of aggressive surveillance, traveler monitoring, airport screening, healthcare preparedness, and rapid containment capabilities.

Travelers utilizing air transit pathways originating in or passing through DRC,

³ 42 CFR 71.40(f).

⁴ 42 CFR 71.40(e)(1) and (3).

Uganda, and South Sudan include non-U.S. citizens, including regional migrants, foreign contract workers, humanitarian personnel, business travelers, students, refugees, and third-country nationals moving through international aviation hubs in Africa, the Middle East, and Europe. Many travelers entering U.S.-bound itineraries from these pathways may do so under temporary visas, refugee or asylum processing mechanisms, international organizational travel, or multi-country itineraries that obscure their original point of departure. As a result, public health screening and border security systems face heightened operational complexity in identifying travelers with recent exposure histories linked to Ebola-affected regions, particularly when travelers originate from or transit through multiple jurisdictions prior to arrival at major U.S. metropolitan airports.

Restricting entry of non-U.S. citizens who originate from or have recently traveled through DRC, Uganda, and South Sudan would reduce the volume of higher-risk international arrivals requiring public health monitoring and follow-up. Limiting the number of potentially exposed travelers entering through major U.S. ports of entry, federal, state, and local public health authorities could concentrate finite surveillance, screening, contact tracing, quarantine management, and medical monitoring resources on returning U.S. citizens and lawful permanent residents. Such an approach would reduce operational strain on airport screening systems, CDC quarantine stations, public health laboratories, and healthcare facilities responsible for evaluating suspected Bundibugyo virus disease cases. It would also improve the ability of authorities to conduct detailed exposure assessments, ensure compliance with monitoring requirements during the 21-day incubation period, rapidly identify symptomatic individuals, and allocate specialized isolation and treatment capacity more effectively. In the context of a rapidly evolving Bundibugyo virus disease outbreak with significant international mobility, prioritizing surveillance efforts toward a smaller and more traceable traveler population would strengthen the overall effectiveness of U.S. disease containment and border health security operations.

IV. Legal Basis for This Order Under Sections 362 and 365 of the Public Health Service Act and 42 CFR 71.40

CDC is issuing this Order pursuant to sections 362 and 365 of the Public Health Service Act (42 U.S.C. 265, 268) and the implementing regulation at 42 CFR 71.40. In accordance with these authorities, the CDC Director is permitted to prohibit, in whole or in part, the introduction into the United States of persons from designated foreign countries (or one or more political subdivisions or regions thereof) or places, only for such period of time that the Director deems necessary to avert the serious danger of the introduction of a quarantinable communicable disease, by issuing an Order in which the Director determines that:

(1) By reason of the existence of any quarantinable communicable disease in a

foreign country (or one or more political subdivisions or regions thereof) or place there is serious danger of the introduction of such quarantinable communicable disease into the United States; and

(2) This danger is so increased by the introduction of persons from such country (or one or more political subdivisions or regions thereof) or place that a suspension of the right to introduce such persons into the United States is required in the interest of public health.⁵

Section 362 and the implementing regulation provide the Director with a public health tool to suspend introduction of persons not only to prevent the introduction of a quarantinable communicable disease, but also to aid in continued efforts to mitigate spread of that disease.⁶

The term “introduction into the United States” is defined in 42 CFR 71.40 as “the movement of a person from a foreign country (or one or more political subdivisions or regions thereof) or place, or series of foreign countries or places, into the United States so as to bring the person into contact with persons or property in the United States, in a manner that the Director determines to present a risk of transmission of a quarantinable communicable disease to persons, or a risk of contamination of property with a quarantinable communicable disease.” 42 CFR 71.40(b)(1). Similarly, the term “serious danger of the introduction of such quarantinable communicable disease into the United States” is defined as, “the probable introduction of one or more persons capable of transmitting the quarantinable communicable disease into the United States, even if persons or property in the United States are already infected or contaminated with the quarantinable communicable disease.” 42 CFR 71.40(b)(3).

Section 71.40(b)(2) defines “[p]rohibit, in whole or in part, the introduction into the United States of persons” in Section 362 to mean “to prevent the introduction of persons into the United States by suspending any right to introduce into the United States, physically stopping or restricting movement into the United States.” *See also* 42 U.S.C. 265 (authorizing the prohibition when the danger posed by the communicable disease “is so increased by the introduction of persons from such country . . . or place that a suspension of the right to introduce such persons into the United States is required in the interest of public health Pursuant to that provision”).⁷

As stated in the Final Rule for 42 CFR 71.40, CDC “may, in its discretion, consider a wide array of facts and circumstances when determining what is required in the interest of public health in a particular situation . . . includ[ing]: the overall number of cases of disease; any large increase in the number of cases over a short period of time; the geographic distribution of cases; any sustained (generational) transmission; the

method of disease transmission; morbidity and mortality associated with the disease; the effectiveness of contact tracing; the adequacy of state and local health care systems; and the effectiveness of state and local public health systems and control measures.”⁸

As stated in 42 CFR 71.40, this Order does not apply to U.S. citizens, U.S. nationals, lawful permanent residents, members of the armed forces of the United States and associated personnel if the Secretary of War provides assurance to the Director that the Secretary of War has taken or will take measures such as quarantine or isolation, or other measures maintaining control over such individuals, to prevent the risk of transmission of the quarantinable communicable disease into the United States, and United States government employees or contractors on orders abroad, or their accompanying family members who are on their orders or are members of their household, if the Director receives assurances from the relevant head of agency and determines that the head of the agency or department has taken or will take measures such as quarantine or isolation, to prevent the risk of transmission of a quarantinable communicable disease into the United States.⁹

In addition, this Order does not apply to additional classes of persons excepted by the CDC Director. Creating exceptions in the Order is consistent with Section 362 and 42 CFR 71.40. Section 362 explicitly states that the prohibition of introduction into the United States may be “in whole or in part.” This phrase is also included in section 71.40(a) and, as explained in the Final Rule, is intended to allow the Director to narrowly tailor the use of the authority to what is required in the interest of public health.¹⁰ Pursuant to this capability, CDC is therefore excepting certain categories of persons, as described herein.

This Order will be in effect for 30 days to avert the serious danger of the introduction, transmission, and spread of Ebola disease into the United States. Finally, as directed by 42 CFR 71.40(c), the Order sets out the following:

(1) The foreign countries (or one or more political subdivisions or regions thereof) or places from which the introduction of persons is being prohibited;

(2) The period of time or circumstances under which the introduction of any persons or class of persons into the United States is being prohibited;

(3) The conditions under which that prohibition on introduction will be effective, in whole or in part, including any relevant exceptions that the Director determines are appropriate;

(4) The means by which the prohibition will be implemented; and

(5) The serious danger posed by the introduction of the quarantinable communicable disease in the foreign country or countries (or one or more political subdivisions or regions thereof) or places from which the introduction of persons is being prohibited.

⁵ 42 U.S.C. 265; 42 CFR 71.40.

⁶ 85 FR 56424 at 56425–26.

⁷ Viral hemorrhagic fevers, which include Ebola, were added to the U.S. federal list of quarantinable communicable diseases by Executive Order 13295 on April 4, 2003.

⁸ *Id.* at 56444.

⁹ 42 CFR 71.40(e) and (f).

¹⁰ 85 FR 56424 at 56444.

V. Determination and Implementation

Based on the foregoing, I hereby determine that Ebola disease, a highly transmissible quarantinable communicable disease, is confirmed present in the DRC and Uganda. There is a material risk that the outbreak will spread to South Sudan. I also determine that the prevalence of Ebola disease in these foreign countries constitutes a serious danger of the introduction of this disease into the United States due to the limited screening and testing and mitigation measures currently available. Finally, I determine that a temporary 30-day suspension of the right to introduce covered aliens is necessary to protect the public health from the serious danger of the introduction of Ebola disease into the United States, pending completion of a thorough public health assessment of the unique public health risk profile posed by Ebola disease and the development of a comprehensive mitigation and containment strategy in consultation with other stakeholders.

I consulted with the Department of State, DHS, and other federal departments as needed before I issued this Order and requested that DHS aid in the enforcement of this Order because CDC does not have the capability, resources, or personnel needed to do so.¹¹ As part of the consultation, DHS developed operational plans for implementing this Order. These plans are consistent with the language of this Order.

Although this Order is not a rule subject to notice and comment under the Administrative Procedure Act (APA) and is issued with immediate effect, in order to ensure that the forthcoming public health risk assessment is informed by public input, the Order is being issued with a simultaneous 30-day comment period.

* * * * *

In testimony whereof, the Senior Official carrying out the delegable duties of the Director, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, has hereunto set his hand at Fairfax County, Virginia this 18th day of May, 2026.

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data so that the public can provide input that may inform the forthcoming public health risk assessment and whether any subsequent exercise of this authority is necessary.

Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be posted on <https://www.regulations.gov>. Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact

information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. Do not submit comments by email. CDC does not accept comment by email.

Authority

The authority for these orders is Sections 362 and 365 of the Public Health Service Act (42 U.S.C. 265, 268).

Jay Bhattacharya,

Senior Official Carrying out the Delegable Duties of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2026-10157 Filed 5-19-26; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-6076]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Required Warnings for Cigarette Packages and Advertisements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by June 22, 2026.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910-0877. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Barrett, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Required Warnings for Cigarette Packages and Advertisements—21 CFR Part 1141

OMB Control Number 0910-0877—Extension

This information collection supports Food and Drug Administration (FDA) regulations and guidance. Tobacco products are governed by chapter IX of the Federal Food, Drug, and Cosmetic Act (sections 900 through 920) (21 U.S.C. 387 through 21 U.S.C. 387t).

On March 18, 2020, FDA issued a final rule establishing new cigarette health warnings for cigarette packages and advertisements entitled “Tobacco Products; Required Warnings for Cigarette Packages and Advertisements” (85 FR 15638; <https://www.federalregister.gov/d/2020-05223>). 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 amended section 4 of the Federal Cigarette Labeling and Advertising Act of 1965 (FCLAA) (15 U.S.C. 1333) to require each cigarette package and advertisement to bear one of the new required warnings. The 2020 final rule specifies the 11 new textual warning label statements and accompanying color graphics.

Section 4(c) of the FCLAA and 21 CFR 1141.10(g) sets forth 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 advertising and requires the submission of plans outlining how the cigarette packaging and advertising will comply with such requirements. FDA must review and approve cigarette plans in advance of any person displaying or distributing cigarette packages or advertisements for products that are required to carry the required warnings,

¹¹ 42 U.S.C. 268; 42 CFR 71.40(d).