

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)	Total burden (in hrs.)
Total					22,550,200

Jeffrey M. Zirger,

*Lead, Information Collection Review Office,
Office of Public Health Ethics and
Regulations, Office of Science, Centers for
Disease Control and Prevention.*

[FR Doc. 2026–21831 Filed 10–26–26; 8:45 am]

BILLING CODE 4163–18–P

**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

**Centers for Disease Control and
Prevention**

**Requirement for Attestation for All
Airline or Other Aircraft Passengers
Arriving in the United States From Any
Foreign Country and Controlled Free
Pratique for Airlines Confirming That
Such Passengers Have Not Been in the
Democratic Republic of the Congo in
the Past 21 Days**

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

ACTION: Notice of Agency Order.

SUMMARY: The Centers for Disease
Control and Prevention (CDC), a
component of the Department of Health
and Human Services (HHS), announces
it is issuing an Order under Sections
361, 365, 368, and 369 of the Public
Health Service Act, and associated
implementing regulations, prohibiting
the boarding of any passenger who is
not otherwise subject to an exemption
on any aircraft destined to the United
States from a foreign country unless the
passenger presents a signed attestation
confirming the passenger has not been
present in the Democratic Republic of
the Congo (DRC) during the 21 days
prior to boarding a flight to the United
States. This Order was issued on
October 22, 2026, to become effective at
11:59 p.m. Eastern Standard Time (EST)
on November 3, 2026, and shall remain
in effect through 11:59 p.m. EST on
December 18, 2026. This Order may be
amended or rescinded prior to that time
at the discretion of the Secretary or his
designee.

DATES: This action will take effect
November 3, 2026, at 11:59 p.m. EST.
For individuals intending to travel to
the United States by air, the Order will
apply to flights departing at or after
11:59 p.m. EST on November 3, 2026.

FOR FURTHER INFORMATION CONTACT:

Mina Zadeh, Acting Chief of Staff,
Centers for Disease Control and
Prevention, 1600 Clifton Road NE, MS
V18–2, Atlanta, GA 30329. Phone: 404–
639–7000. Email: cdcregulations@cdc.gov.

SUPPLEMENTARY INFORMATION: On

October 22, 2026, the Assistant
Secretary for Health (ASH), HHS, signed
an Order prohibiting the boarding of any
passenger on any aircraft destined to the
United States from a foreign country
unless the passenger presents a signed
attestation in paper or digital format
confirming that the passenger has not
been present in the Democratic Republic
of the Congo (DRC) during the 21 days
prior to boarding a flight to the United
States. This includes any flight arriving
in the United States, regardless of
whether the United States is its final
destination or the flight is connecting
through the United States en route to
another country. The airline or aircraft
operator must retain a copy of the
completed version of the signed
attestation for at least 42 days after the
passenger's flight departs for the United
States from a foreign country and
provide the attestation to the U.S.
Government upon request.

This Order is effective for a period of
45 days. This Order may be amended or
rescinded prior to that time at the
discretion of the Secretary or his
designee. Any amendment or extension
of this Order will be based on the
current outbreak metrics, including case
counts, geographic spread, community-
transmission indicators, and
containment capacity in affected
countries.

Pursuant to 42 U.S.C. 268, the U.S.
customs officers and U.S. Coast Guard
officers will assist in implementation of
this Order. Other federal departments
and agencies, including the U.S.
Department of Homeland Security and
the U.S. Department of Transportation,
may also cooperate and assist with
implementation of this Order consistent
with their own legal authorities.

This Order shall be enforceable
through the provisions of 18 U.S.C.
3559, 3571; 42 U.S.C. 243, 268, 270,
271; and 42 CFR 71.2. Pursuant to 42
U.S.C. 271, CDC may request the U.S.
Department of Justice seek to prosecute
individuals who knowingly and

willfully submit false attestations in
violation of 18 U.S.C. 1001.

This Order is not a rule within the
meaning of the Administrative
Procedure Act (“APA”) but rather is an
action taken under the existing
authority of 42 U.S.C. 264(a) and 42 CFR
71.20, 71.31(b), and 71.32(b), which
were promulgated in accordance with
the APA after full notice and comment
rulemaking and a delayed effective date.
Separately, HHS/CDC is issuing a
Paperwork Reduction Act (PRA) notice
related to the attestation form required
under this Order. The PRA notice also
published in today's issue of the
Federal Register and provides an
opportunity for public comment
through www.regulations.gov.

A copy of the Order is provided below
and a copy of the signed Order can be
found at <https://www.cdc.gov/port-health/legal-authorities/attestation-order.html>.

**Centers for Disease Control and
Prevention (CDC)**

**Department of Health and Human
Services (HHS)**

**Notice and Order Under Sections 361,
365, 368, & 369 of the Public Health
Service Act (42 U.S.C. 264, 268, 270, &
271) and 42 Code of Federal
Regulations 71.20, 71.31(b), & 71.32(b)**

**Requirement for Attestation for all
Airline or Other Aircraft Passengers
Arriving in the United States From any
Foreign Country and Controlled Free
Pratique for Airlines Confirming That
Such Passengers Have Not Been in the
Democratic Republic of the Congo in
the Past 21 Days**

Summary

Pursuant to 42 CFR 71.20, 71.31(b),
and 71.32(b), and as set forth in greater
detail below, this Notice and Order
prohibit the boarding of any passenger
who is not otherwise subject to an
exemption on any aircraft destined to
the United States from a foreign country
unless the passenger presents:

- A signed attestation in paper or
digital format confirming that the
passenger has not been present in the
Democratic Republic of the Congo (DRC)
during the 21 days prior to boarding a
flight to the United States.

This includes any flight arriving in the United States, regardless of whether the United States is its final destination or the flight is connecting through the United States en route to another country. This Order does not apply to overflights that do not land at any airport in the United States.

Further, pursuant to 42 CFR 71.31(b) and as set forth in greater detail below, this Notice and Order operates as a controlled free pratique requiring an airline or other aircraft operator with an aircraft arriving into the United States to confirm to the U.S. Government that every passenger onboard the aircraft has completed and signed an attestation confirming that the passenger has not been in the DRC during the 21 days prior to boarding the flight to the United States as a condition of the airline or aircraft operator being granted permission to enter a U.S. port of entry, disembark passengers, and begin operations with respect to arriving at a U.S. airport.

A parent or other authorized individual may complete and sign the required attestation on behalf of a passenger under 18 years of age. An authorized individual may also act on behalf of any passenger who is unable to act on their own behalf (e.g., by reason of age, or physical or mental impairment).

The passenger must provide the airline or aircraft operator with a paper or digital copy of the completed attestation reflecting that the passenger has not been present in the DRC in the past 21 days prior to boarding a flight to the United States. The airline or aircraft operator must retain the paper or digital copy of each passenger's completed and signed attestation for at least 42 days after the passenger's flight departs for the United States from a foreign country and provide the attestation to the U.S. Government upon request.

CDC encourages airlines and aircraft operators to incorporate the attestation into paperless check-in processes. An airline or aircraft operator may use a third party (including a third-party digital application) to provide translations. However, an airline or aircraft operator has sole legal responsibility to ensure the accuracy of any translation and to comply with all other obligations under this Order. An airline or aircraft operator is responsible for any failure to comply with its responsibilities as set forth in this Order, including for actions of a third party used to help effectuate its compliance with this Order. As between the airline or aircraft operator and the U.S. Government, the airline or aircraft

operator remains responsible for compliance with this Order regardless of the involvement of any third party.

Pursuant to 42 U.S.C. 268, customs officers and U.S. Coast Guard officers will assist in the implementation of this Order. Other federal departments and agencies, including the U.S. Department of Homeland Security and the U.S. Department of Transportation, may also cooperate and assist with implementation of this Order consistent with their own legal authorities.

The U.S. Department of Justice may seek to prosecute individuals who knowingly and willfully submit false attestations in violation of 18 U.S.C. 1001.

Relationship to Other Orders

This Order operates in addition to, and does not supersede, modify, or replace, other CDC orders currently in effect concerning Ebola disease caused by the Bundibugyo virus, including the Order Suspending the Right to Introduce Certain Persons from Countries Where a Quarantinable Communicable Disease Exists issued pursuant to 42 U.S.C. 265, 268 and 42 CFR 71.40, as most recently continued. Nothing in this Order limits the authority of CDC, the Department of State, the Department of Homeland Security, the Department of Transportation, or any other federal department or agency to take additional measures under their own separate legal authority.

Statement of Intent

This Order shall be interpreted and implemented to achieve the following paramount objectives:

- Preservation of human life;
- Preventing the introduction, transmission, and spread of the Ebola virus into the United States; and
- Preserving the health and safety of crew members, passengers, airport personnel, and communities.

Definitions

21 days for purposes of the passenger attestation means a 21-day waiting period based on calendar days. Day 0 is the day the individual departed the DRC. Day 1 is the first full calendar day the individual is outside the DRC. An individual who was present in the DRC may board a flight to the United States on day 22.

Aircraft shall have the same definition as under 49 U.S.C. 40102(a)(6). "Aircraft" includes, but is not limited to, commercial, general aviation, and private aircraft destined for the United States from a foreign country.

Aircraft Operator means an individual or organization causing or authorizing the operation of an aircraft.

Airline shall have the same definition as under 42 CFR 71.1(b).

Attest/Attestation means completion and signature of the attestation in Attachment A. Such attestation may be completed and signed in paper or digital form, including through electronic signature. The attestation is a statement, writing, entry, or other representation made under 18 U.S.C. 1001.

Foreign country means anywhere that is not a state, territory, or possession of the United States.

Present/Presence in the DRC means any physical presence, including entering or traveling through the country by air (excluding overflights), land, or sea. Presence also includes connecting through an airport in the DRC, even if the passenger did not disembark the plane or leave the airport.

United States has the same definition as "United States" in 42 CFR 71.1(b), meaning "the 50 States, District of Columbia, and the territories (also known as possessions) of the United States, including American Samoa, Guam, the Northern Mariana Islands, the Commonwealth of Puerto Rico, and the U.S. Virgin Islands."

Exemptions

The following are exempt from the requirements of this Order:

- Aircraft operators transporting passengers with Ebola disease pursuant to U.S. Government authorization and in accordance with CDC guidance.
- Individuals for whom the CDC has issued an exemption based on humanitarian or other important government considerations, e.g., emergency medical evacuations. Additional conditions may be placed on individuals granted such exemptions, including but not limited to, observing precautions during travel, providing consent to post-arrival monitoring, and/or self-quarantine after arrival in the United States, as may be directed by federal, state, territorial, tribal or local public health authorities to reduce the risk of disease transmission.

Background

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, and Lassa fever.

Bundibugyo virus disease (BVD) is a severe and often fatal illness caused by

one of the 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. BVD 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 BVD 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 BVD until symptoms begin.

Screening for BVD focuses on identifying symptoms and possible exposure history, such as recent travel to affected areas or contact with infected individuals. Patients with suspected BVD 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 and contact tracing to identify suspected cases, and quarantine and isolation procedures, as applicable, to prevent transmission.

There are currently no widely approved vaccines or specific antiviral treatments for BVD. 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. Clinical trials of monoclonal antibodies and of an existing vaccine approved for use to prevent disease caused by the Ebola Zaire virus are presently underway in the DRC.^{1 2}

¹ World Health Organization. *Patient enrolment begins in a scientific trial to identify the first effective treatments for Bundibugyo virus disease*, <https://www.who.int/news/item/02-07-2026-patient-enrolment-begins-in-a-scientific-trial-to-identify-the-first-effective-treatments-for-bundibugyo-virus-disease> (last accessed October 13, 2026).

However, experts expect it will be several months before these therapeutics are potentially available for wider use.

B. Ongoing Bundibugyo Virus Disease Outbreak

The confirmed ongoing outbreak of BVD in the DRC continues to escalate in intensity. The outbreak remains centered in eastern DRC's Ituri Province, although cases have been identified in North Kivu, South Kivu, Haut-Uélé, Bas-Uélé, Tshopo, North Ubangi, and South Ubangi provinces. This geographic expansion is concerning, particularly given that response efforts are still not at the scale required for outbreak containment. As of October 18, 2026, the DRC reports 9,455 confirmed cases and 4,561 deaths in 66 health zones across eight provinces.

The World Health Organization has reported substantial under-ascertainment of cases and persistent challenges with contact tracing. As of its most recent assessment, only approximately 20 percent of BVD cases were identified through follow-up of listed contacts, and approximately 40 percent were ultimately linked to a known chain of transmission, indicating substantial undetected transmission.³ Surveillance challenges persist in the most heavily affected areas, with conflict and insecurity, weak health infrastructure, and relatively porous borders in the region complicating containment efforts. Although contact tracing efforts are underway, they remain insufficient and the daily follow-up necessary to rapidly detect symptomatic individuals and ensure their prompt isolation has not been achieved.

Travelers who have unknowingly been infected with BVD may travel before becoming symptomatic. Such travelers may spread the virus beyond DRC and ultimately reach the United States. The DRC is connected to the global aviation network through a series of regional and international transit hubs that provide pathways into the United States. These international transportation corridors support continuous movement of travelers between Central and East Africa and

major U.S. metropolitan centers, increasing the likelihood that travelers exposed to Ebola 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 BVD introduction into the United States is heightened by the virus's incubation period, which can extend up to 21 days, allowing infected persons to travel internationally while asymptomatic and therefore unlikely to be detected through routine symptom-based screening measures. The current outbreak has demonstrated this risk: for example, a physician infected while providing patient care in the DRC traveled internationally before becoming ill and was diagnosed only after arriving in France.⁴ That case required extensive public health coordination, including federal, state, and local government efforts to identify, notify, and monitor potentially exposed U.S. citizens, demonstrating that a single infected traveler can impose significant cross-border public health response demands even without onward transmission occurring within the United States. Additionally, on October 6, 2026, the Kenya Ministry of Health announced the country's first BVD case and death in an individual who had traveled from DRC to Uganda, flown from Kampala to Nairobi on October 2, and was hospitalized before dying on October 5, 2026.⁵ By October 19, 2026, Kenya had announced another seven cases had been confirmed in previously identified close contacts, reaching a total of eight BVD cases in Kenya, including the initial case that resulted in a death.⁶ The interconnected nature of global air travel presents a credible pathway for BVD importation into the United States, underscoring the importance of aggressive surveillance, traveler monitoring, airport public health screening, healthcare preparedness, and rapid containment capabilities.

⁴ World Health Organization, *WHO Director-General's opening remarks at the media briefing—24 June 2026*, available at <https://www.who.int/news-room/speeches/item/who-director-general-s-opening-remarks-at-the-media-briefing--24-june-2026> (last accessed October 13, 2026).

⁵ World Health Organization, *Kenya confirms first imported Bundibugyo virus disease case; WHO supports control efforts*, <https://www.afro.who.int/countries/kenya/news/kenya-confirms-first-imported-bundibugyo-virus-disease-case-who-supports-control-efforts> (last accessed October 13, 2026).

⁶ Ebola cases in Kenya rise to 8 after another person tests positive, <https://apnews.com/article/kenya-ebola-congo-uganda-0b235bf00d39345037f2d298e92e24f>.

² United Nations. *Ebola vaccine research programme begins in DR Congo*, <https://news.un.org/en/story/2026/09/1168381> (last accessed October 13, 2026).

³ Second meeting of the IHR Emergency Committee on the epidemic of Ebola Bundibugyo virus disease in the Democratic Republic of the Congo—Meeting report <https://www.who.int/news/item/28-08-2026-second-meeting-of-the-ihremergency-committee-on-the-epidemic-of-ebola-bundibugyo-virus-disease-in-the-democratic-republic-of-the-congo-meeting-report> (last accessed October 13, 2026).

The ongoing outbreak has also demonstrated that substantial U.S. public health resources may be required to respond to an Ebola exposure or infection in any U.S. citizen. On July 10, 2026, CDC announced that an additional U.S. citizen working for a humanitarian organization in the DRC had tested positive for BVD.⁷ The individual, who was not involved in direct patient care,⁸ prompted an extensive U.S. public health response. CDC, in coordination with the humanitarian organization, initiated contact tracing, exposure risk assessments, and monitoring activities to identify high-risk contacts and evaluate potential exposures among humanitarian personnel who had recently returned to, or are planning to return to, the United States. The Department of State arranged medical evacuation outside of the DRC for treatment. This incident demonstrates that even when an infected U.S. citizen remains overseas, the outbreak can require substantial U.S. public health resources to identify, assess, and monitor potentially exposed individuals associated with international humanitarian operations.

Travelers utilizing air transit pathways originating in the DRC include U.S. and non-U.S. citizens, 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 transit through multiple jurisdictions prior to arrival at major U.S. metropolitan airports.

CDC has issued Travel Health Notices (THN) for affected countries and regions. Currently, there is a Level 4 THN for Ituri and Nord-Kivu Provinces

of DRC (avoid all travel); a Level 3 THN for Haut-Uélé and Tshopo Provinces of DRC (reconsider nonessential travel); a Level 2 THN (practice enhanced precautions) for the remainder of the DRC and Uganda; and a Level 1 THN (practice usual precautions) for Nairobi, Kenya.⁹ CDC modeling indicates that, absent rapid and sustained public health interventions, the outbreak could become one of the largest Ebola epidemics ever recorded.¹⁰ The analysis further demonstrates that early identification of cases, contact tracing, isolation, and treatment of symptomatic persons, community engagement, and safe burial practices are critical to reducing transmission and mitigating outbreak growth.¹¹ CDC has concluded that the current outbreak is already the largest known outbreak of BVD and that large-scale, temporary public health measures are necessary to prevent further international spread of the disease and to reduce the risk of introduction of infected persons into the United States.¹² Commensurate with the deterioration of the epidemiological situation in the DRC, CDC escalated its response to the outbreak to a Level 1, the highest level within the agency's Graduated Response Framework.¹³

CDC has determined that the risk profile presented by the DRC is materially distinct from that of other affected countries. The DRC remains the epicenter of the outbreak, with an estimated 80 percent of newly confirmed cases in Ituri Province not linked to known contacts, indicating substantial undetected community transmission. Contact tracing, surveillance, and containment capacity in the DRC are impaired by conflict, insecurity, weak health infrastructure, and porous borders. CDC has therefore determined that a categorical temporary measure directed at travelers with recent presence in the DRC is appropriately tailored to the elevated importation risk presented by that country. CDC will continue to monitor conditions in the DRC and other affected countries and may modify the scope of this Order accordingly.

Statement of Good Cause Under the Administrative Procedure Act

This Order is not a rule within the meaning of the Administrative Procedure Act ("APA") but rather is an action taken under the existing authority of 42 U.S.C. 264(a) and 42 CFR 71.20, 71.31(b), and 71.32(b), which were promulgated in accordance with the APA after full notice and comment rulemaking and a delayed effective date. If this Order qualifies as a new rule under the APA, notice and comment and a delayed effective date are not required because there is good cause to dispense with prior public notice and comment and a delay in effective date. See 5 U.S.C. 553(b)(B), (d)(3).

Based on the foregoing, I have determined that Ebola disease caused by the Bundibugyo virus, a highly transmissible quarantinable communicable disease designated as such by Executive Order 13295, as amended, is confirmed present in the DRC. I have also determined that Ebola disease if introduced into the United States would constitute a public health emergency. I have considered other alternatives, including reliance on airport-based public health screening, voluntary questioning, and expansion of the existing federal public health travel restrictions process, and have determined that these alternatives, standing alone or in combination, would not adequately address the identified risk given the disease's incubation period of up to 21 days, the substantial proportion of asymptomatic transmission-window travel, and the demonstrated capacity of a single infected traveler to consume substantial U.S. public health resources. Finally, I determine that requiring airline passengers to submit an attestation confirming that they have not been present in the DRC during the 21 days prior to boarding a flight to the United States, combined with a conditioning of controlled free pratique on airline confirmation of such attestations, is a necessary public health measure to protect the public health and prevent the introduction, transmission, and spread of Ebola disease into the United States. In making these determinations I have considered the prevalence of Ebola disease in the DRC, that country's limited ability to screen for the disease and engage in other mitigation measures, and the potential for spread in the United States. Accordingly, I find that any delay in issuing this Order beyond the minimum necessary for operationally feasible implementation would be contrary to the public's health

⁷ CDC, CDC Statement on Ebola Outbreak in the Democratic Republic of Congo and Uganda: 7/10/26, <https://www.cdc.gov/media/releases/2026/cdc-ebola-outbreak-in-democratic-republic-of-congo-and-uganda.html> (last accessed October 13, 2026).

⁸ Walsh, D. and Yoon, J., *U.S. Citizen Tests Positive for Ebola in Democratic Republic of Congo*, https://www.nytimes.com/2026/07/11/world/africa/dr-congo-ebola-american-us-citizen.html?unlocked_article_code=1.w1A.A4kv.spNP2lf8jap6&smid=url-share (last accessed October 13, 2026).

⁹ CDC Travel Health Notices, <https://wwwnc.cdc.gov/travel/notices>.

¹⁰ Mooring EQ, Koval WT, Routledge I, et al. *Modeled Scenario Projections for the Ebola Disease Outbreak Caused by Bundibugyo Virus, 2026*. MMWR Morb. Mortal Wkly. Rep. 2026;75:285–289. DOI: <http://dx.doi.org/10.15585/mmwr.mm7522e1>.

¹¹ Id.

¹² Id.

¹³ CDC, Internal Decision Memo, June 26, 2026.

in the United States and therefore the public's interest.

Any delay in the effective date, would be impracticable and contrary to the public interest for the additional reason that the outbreak in the DRC continues to expand, the 21-day incubation period of Ebola disease means that each additional day of pre-effective delay materially increases the risk that infected persons will board flights bound for the United States while asymptomatic, and public notice of a forthcoming attestation requirement could prompt individuals presently in the DRC to accelerate their travel to the United States before the requirement takes effect, defeating the purpose of this Order.

If any provision of this Order, or the application of any provision to any carriers, persons, or circumstances, shall be held invalid, the remainder of the provisions, or the application of such provisions to any carriers, persons, or circumstances other than those to which it is held invalid, shall remain valid and in effect.

Pursuant to 5 U.S.C. 553(b)(B), and for the reasons stated above, I hereby conclude that notice-and-comment rulemaking would defeat the purpose of the Order and endanger the public health, and is, therefore, impracticable and contrary to the public interest. For the same reasons, I have determined, consistent with 5 U.S.C. 553(d)(3), that there is good cause to make this Order effective immediately following the minimum delay necessary for the Order's implementation to be operationally feasible.

Action

For the reasons outlined above, I hereby determine that passengers covered by this Order are at risk of transmitting Ebola disease and requiring passengers to attest that they have not been present in the DRC during the 21 days prior to boarding a flight to the United States is needed as a public health measure to protect the health of other travelers and U.S. communities.

This Order shall remain in effect until rescinded or modified based on specific public health or other considerations, or until December 17, 2026, whichever occurs first. Any amendment or extension of this Order will be based on a review of then-current outbreak metrics, including case counts, geographic spread, community-transmission indicators, and containment capacity in affected countries.

1. Requirements for Airlines & Other Aircraft Operators

This Order conditions the grant of controlled free pratique on the airline compliance measures specified below. This Order does not regulate landing rights, airspace access, or aircraft certification, which remain within the jurisdiction of the Department of Transportation, the Federal Aviation Administration, and other agencies exercising their respective legal authorities.

Any airline or other aircraft operator with passengers who are not otherwise exempt from the requirements of this Order boarding a flight to the United States from a foreign country, shall:

A. Confirm to the U.S. Government, at or before the time of boarding, that all passengers boarding or onboard the aircraft have completed and signed an attestation in paper or digital format confirming that they have not been present in the Democratic Republic of the Congo (DRC) during the 21 days preceding their boarding a flight to the United States. For purposes of this requirement, "confirm" means that the airline or aircraft operator has reviewed the completed attestation from each covered passenger prior to boarding and has determined, based on the face of the attestation, that the attestation is complete and signed; and

B. Not board any passenger who has failed to complete and present such an attestation.

C. Retain a paper or digital copy each passenger's completed and signed attestation for at least 42 days after the passenger's flight departs for the United States from a foreign country and provide the attestation to the U.S. Government on request.

Any airline or other aircraft operator that fails to comply with section 1, "Requirements for Airlines & Other Aircraft Operators," may be subject to criminal penalties under, *inter alia*, 42 U.S.C. 270 and 271 and 42 CFR 71.2, in conjunction with 18 U.S.C. 3559 and 3571 (providing for fines of up to \$100,000 for individuals and \$200,000 for organizations, and/or imprisonment of up to one year). CDC anticipates that separate compliance mechanisms may be established by the Transportation Security Administration pursuant to its own statutory authorities.

Any airline or other aircraft operator that fails to provide the U.S. Government the confirmation of completed attestations of all passengers as outlined above will not receive controlled free pratique to enter a U.S. port of entry, disembark passengers, and

begin operation with respect to arriving at an airport in the United States.

2. Requirements for Aircraft Passengers Who Are Not Otherwise Exempt

A. Complete and sign the attestation under penalty of law as provided by 18 U.S.C. 1001 which provides criminal penalties for knowingly and willfully submitting false statements to the U.S. government; and

B. Provide for confirmation the completed and signed attestation to the airline or other aircraft operator confirming that they have not been present in the Democratic Republic of the Congo (DRC) during the 21 days preceding their boarding a flight to the United States.

The required attestation text is attached to this Order as Attachment A. Unless otherwise permitted by law, a parent or other authorized individual may present the required documentation on behalf of a passenger under 18 years of age. An authorized individual may act on behalf of any passenger who is unable to act on their own behalf (*e.g.*, by reason of age, or physical or mental impairment).

Any passenger who fails to provide this attestation, or submits false or misleading information, may face a delay of travel, denial of boarding, or denial of boarding on future travel.

Any passenger who fails to comply with the requirements of section 2, "Requirements for Aircraft Passengers," may be subject to criminal penalties under, *inter alia*, 42 U.S.C. 271 and 42 CFR 71.2, in conjunction with 18 U.S.C. 3559 and 3571. Willfully giving false or misleading information to the government may result in criminal penalties under, *inter alia*, 18 U.S.C. 1001. This Order shall be enforceable through the provisions of 18 U.S.C. 3559, 3571; 42 U.S.C. 243, 268, 270, 271; and 42 CFR 71.2. The U.S. Department of Justice in its discretion may prosecute any individual who knowingly and willfully submits a false statement in violation of 18 U.S.C. 1001.

Effective Date

This Order takes effect at 11:59 p.m. Eastern Standard Time on November 3, 2026. For individuals intending to travel to the United States by air, the Order will apply to flights departing at or after 11:59 p.m. Eastern Standard Time on November 3, 2026.

In testimony whereof, the Assistant Secretary for Health, U.S. Department of Health and Human Services, has hereunto set his hand at _____, this October 22, 2026.

Admiral Brian Christine, MD,
Assistant Secretary for Health (ASH)

and Head of the United States Public Health Service (USPHS) Commissioned Corps, Department of Health and Human Services.

Authority

The authority for this order is Sections 361, 365, 368, and 369 of the Public Health Service Act (42 U.S.C. 264, 268, 270, and 271), as amended.

Brian Christine,

Assistant Secretary for Health (ASH) and Head of the United States Public Health Service (USPHS) Commissioned Corps, Department of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–P–7178]

Determination That PEPCID RPD (Famotidine) Orally Disintegrating Tablets, 20 Milligrams and 40 Milligrams Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) has determined that PEPCID RPD (famotidine) orally disintegrating tablets, 20 milligrams (mg) and 40 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for famotidine orally disintegrating tablets, 20 mg and 40 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions)

labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the “Approved Drug Products With Therapeutic Equivalence Evaluations,” which is known generally as the “Orange Book.” Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

PEPCID RPD (famotidine) orally disintegrating tablets, 20 mg and 40 mg, are the subject of NDA 020752, held by Merck & Co., Inc., and initially approved on May 29, 1998. PEPCID RPD is indicated for short term treatment of active duodenal ulcer, maintenance therapy for duodenal ulcer patients at reduced dosage after healing of an active ulcer, short term treatment of active benign gastric ulcer, short term treatment of gastroesophageal reflux disease, and treatment of pathological hypersecretory conditions (e.g., Zollinger-Ellison Syndrome, multiple endocrine adenomas).

In a letter dated September 11, 2013, Merck Sharp & Dohme Corp., (Merck) notified FDA that PEPCID RPD (famotidine) orally disintegrating tablets, 20 mg and 40 mg, were being discontinued, and FDA moved the drug product to the “Discontinued Drug Product List” section of the Orange Book. In the same letter, Merck Sharp requested withdrawal of NDA 020752 for PEPCID RPD (famotidine) orally disintegrating tablets, 20 mg and 40 mg. In the **Federal Register** of June 21, 2017 (82 FR 28322), FDA announced that it was withdrawing approval of NDA 020752, effective July 21, 2017.

Lachman Consultant Services, Inc. submitted a citizen petition dated June

29, 2026 (Docket No. FDA–2026–P–7178), under 21 CFR 10.30, requesting that the Agency determine whether PEPCID RPD (famotidine) orally disintegrating tablets, 20 mg and 40 mg, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that PEPCID RPD (famotidine) orally disintegrating tablets, 20 mg and 40 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that these drug products were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of PEPCID RPD (famotidine) orally disintegrating tablets, 20 mg and 40 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list PEPCID RPD (famotidine) orally disintegrating tablets, 20 mg and 40 mg, in the “Discontinued Drug Product List” section of the Orange Book. The “Discontinued Drug Product List” delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to these drug products may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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