DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

19 CFR Chapter I

Notification of Temporary Travel Restrictions Applicable To Land Ports of Entry and Ferries Service Between the United States and Canada

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

ACTION: Notification of continuation of temporary travel restrictions.

SUMMARY: This document announces the decision of the Secretary of Homeland Security (Secretary) to continue to temporarily limit the travel of individuals from Canada into the United States at land ports of entry along the United States-Canada border. Such travel will be limited to ''essential travel,'' as further defined in this document.

DATES: These restrictions go into effect at 12 a.m. Eastern Daylight Time (EDT) on July 22, 2020 and will remain in effect until 11:59 p.m. EDT on August 20, 2020.

FOR FURTHER INFORMATION CONTACT: Alyce Modesto, Office of Field Operations, U.S. Customs and Border Protection (CBP) at 202–344–3788.

SUPPLEMENTARY INFORMATION:

Background

On March 24, 2020, DHS published notice of the Secretary's decision to temporarily limit the travel of individuals from Canada into the United States at land ports of entry along the United States-Canada border to ''essential travel,'' as further defined in that document.[1] The document described the developing circumstances regarding the COVID–19 pandemic and stated that, given the outbreak and continued transmission and spread of the virus associated with COVID–19 within the United States and globally, the Secretary had determined that the risk of continued transmission and spread of the virus associated with COVID–19 between the United States and Canada posed a ''specific threat to human life or national interests.'' The Secretary later published a series of notifications continuing such limitations on travel until 11:59 p.m. EDT on July 21, 2020.[2]

The Secretary has continued to monitor and respond to the COVID–19 pandemic. As of July 16, there are over 13.3 million confirmed cases globally, with over 580,000 confirmed deaths.[3] There are over 3.4 million confirmed and probable cases within the United States,[4] over 108,000 confirmed cases in Canada,[5] and over 311,000 confirmed cases in Mexico.[6]

Notice of Action

Given the outbreak and continued transmission and spread of COVID–19 within the United States and globally, the Secretary has determined that the risk of continued transmission and spread of the virus associated with COVID–19 between the United States and Canada poses an ongoing ''specific threat to human life or national interests.''

U.S. and Canadian officials have mutually determined that non-essential travel between the United States and Canada poses additional risk of transmission and spread of the virus associated with COVID–19 and places the populace of both nations at increased risk of contracting the virus associated with COVID–19. Moreover, given the sustained human-to-human transmission of the virus, returning to previous levels of travel between the two nations places the personnel staffing land ports of entry between the United States and Canada, as well as the individuals traveling through these ports of entry, at increased risk of exposure to the virus associated with COVID–19. Accordingly, and consistent with the authority granted in 19 U.S.C. 1318(b)(1)(C) and (b)(2),[7] I have determined that land ports of entry along the U.S.-Canada border will continue to suspend normal operations and will only allow processing for entry into the United States of those travelers engaged in ''essential travel,'' as defined below. Given the definition of ''essential travel'' below, this temporary alteration in land ports of entry operations should not interrupt legitimate trade between the two nations or disrupt critical supply chains that ensure food, fuel, medicine, and other critical materials reach individuals on both sides of the border.

For purposes of the temporary alteration in certain designated ports of entry operations authorized under 19 U.S.C. 1318(b)(1)(C) and (b)(2), travel through the land ports of entry and ferry terminals along the United States-Canada border shall be limited to ''essential travel,'' which includes, but is not limited to—

- U.S. citizens and lawful permanent residents returning to the United States;
- Individuals traveling for medical purposes (*e.g.,* to receive medical treatment in the United States);
- Individuals traveling to attend educational institutions;
- Individuals traveling to work in the United States (*e.g.,* individuals working in the farming or agriculture industry who must travel between the United States and Canada in furtherance of such work);
- Individuals traveling for emergency response and public health purposes (*e.g.,* government officials or emergency responders entering the United States to support federal, state, local, tribal, or territorial government efforts to respond to COVID–19 or other emergencies);
- Individuals engaged in lawful cross-border trade (*e.g.,* truck drivers

[1] 85 FR 16548 (Mar. 24, 2020). That same day, DHS also published notice of the Secretary's decision to temporarily limit the travel of individuals from Mexico into the United States at land ports of entry along the United States-Mexico border to ''essential travel,'' as further defined in that document. 85 FR 16547 (Mar. 24, 2020).

[2] *See* 85 FR 37744 (June 24, 2020); 85 FR 31050 (May 22, 2020); 85 FR 22352 (Apr. 22, 2020). DHS also published parallel notifications of the Secretary's decisions to continue temporarily limiting the travel of individuals from Mexico into the United States at land ports of entry along the United States-Mexico border to ''essential travel.'' *See* 85 FR 37745 (June 24, 2020); 85 FR 31057 (May 22, 2020); 85 FR 22353 (Apr. 22, 2020).

[3] WHO, Coronavirus disease 2019 (COVID–19) Situation Report—178 (July 16, 2020), available at *https://www.who.int/docs/default-source/coronaviruse/situation-reports/20200716-covid-19-sitrep-178.pdf?sfvrsn=28ee165b_2.*

[4] CDC, Cases of COVID–19 in the U.S. (last updated July 16, 2020), available at *https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html.*

[5] WHO, Coronavirus disease 2019 (COVID–19) Situation Report—178 (July 16, 2020).

[6] *Id.*

[7] 19 U.S.C. 1318(b)(1)(C) provides that ''[n]otwithstanding any other provision of law, the Secretary of the Treasury, when necessary to respond to a national emergency declared under the National Emergencies Act (50 U.S.C. 1601 *et seq.*) or to a specific threat to human life or national interests,'' is authorized to ''[t]ake any . . . action that may be necessary to respond directly to the national emergency or specific threat.'' On March 1, 2003, certain functions of the Secretary of the Treasury were transferred to the Secretary of Homeland Security. *See* 6 U.S.C. 202(2), 203(1). Under 6 U.S.C. 212(a)(1), authorities ''related to Customs revenue functions'' were reserved to the Secretary of the Treasury. To the extent that any authority under section 1318(b)(1) was reserved to the Secretary of the Treasury, it has been delegated to the Secretary of Homeland Security. *See* Treas. Dep't Order No. 100–16 (May 15, 2003), 68 FR 28322 (May 23, 2003). Additionally, 19 U.S.C. 1318(b)(2) provides that ''[n]otwithstanding any other provision of law, the Commissioner of U.S. Customs and Border Protection, when necessary to respond to a specific threat to human life or national interests, is authorized to close temporarily any Customs office or port of entry or take any other lesser action that may be necessary to respond to the specific threat.'' Congress has vested in the Secretary of Homeland Security the ''functions of all officers, employees, and organizational units of the Department,'' including the Commissioner of CBP. 6 U.S.C. 112(a)(3).

supporting the movement of cargo between the United States and Canada);

- Individuals engaged in official government travel or diplomatic travel;
- Members of the U.S. Armed Forces, and the spouses and children of members of the U.S. Armed Forces, returning to the United States; and
- Individuals engaged in military-related travel or operations.

The following travel does not fall within the definition of ''essential travel'' for purposes of this Notification—

- Individuals traveling for tourism purposes (*e.g.,* sightseeing, recreation, gambling, or attending cultural events).

At this time, this Notification does not apply to air, freight rail, or sea travel between the United States and Canada, but does apply to passenger rail, passenger ferry travel, and pleasure boat travel between the United States and Canada. These restrictions are temporary in nature and shall remain in effect until 11:59 p.m. EDT on August 20, 2020. This Notification may be amended or rescinded prior to that time, based on circumstances associated with the specific threat.

The Commissioner of U.S. Customs and Border Protection (CBP) is hereby directed to prepare and distribute appropriate guidance to CBP personnel on the continued implementation of the temporary measures set forth in this Notification. The CBP Commissioner may determine that other forms of travel, such as travel in furtherance of economic stability or social order, constitute ''essential travel'' under this Notification. Further, the CBP Commissioner may, on an individualized basis and for humanitarian reasons or for other purposes in the national interest, permit the processing of travelers to the United States not engaged in ''essential travel.''

The Acting Secretary of Homeland Security, Chad F. Wolf, having reviewed and approved this document, is delegating the authority to electronically sign this document to Chad R. Mizelle, who is the Senior Official Performing the Duties of the General Counsel for DHS, for purposes of publication in the **Federal Register**.

Chad R. Mizelle,

Senior Official Performing the Duties of the General Counsel, U.S. Department of Homeland Security.

[FR Doc. 2020–15955 Filed 7–21–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 884, 888, and 890

[Docket No. FDA–2019–N–2686]

Medical Devices; Exemptions From Premarket Notification: Class II Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is publishing an order setting forth the Agency's final determination to exempt a list of class II devices from premarket notification (510(k)) requirements, subject to certain limitations. This exemption from 510(k), subject to certain limitations, is immediately in effect for the list of class II devices. The exemption will decrease regulatory burdens on the medical device industry and will eliminate private costs and expenditures required to comply with certain Federal regulations. FDA is also amending the codified language for the list of class II devices to reflect this final determination. FDA is publishing this order in accordance with the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: This order is effective July 22, 2020.

FOR FURTHER INFORMATION CONTACT: Jismi Johnson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1528, Silver Spring, MD 20993, 301–796–6424, *Jismi.johnson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and its implementing regulations in part 807, subpart E (21 CFR part 807, subpart E), persons who propose to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use are required to submit a 510(k) to FDA. The device may not be marketed until FDA finds it ''substantially equivalent'' within the meaning of section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a legally marketed device that does not require premarket approval.

On December 13, 2016, the 21st Century Cures Act (Cures Act) (Pub. L. 114–255) was signed into law. Section 3054 of the Cures Act amended section 510(m) of the FD&C Act. As amended, section 510(m)(2) of the FD&C Act provides that, 1 calendar day after the date of publication of the final list under section 510(m)(1)(B) of the FD&C Act,[1] FDA may exempt a class II device from the requirement to submit a report under section 510(k) of the FD&C Act, upon its own initiative or a petition of an interested person, if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device. This section requires FDA to publish in the **Federal Register** a notice of intent to exempt a device, or of the petition, and provide a 60-calendar-day comment period. Within 120 days of publication of such notice, FDA shall publish an order in the **Federal Register** that sets forth its final determination regarding the exemption of the device that was the subject of the notice.

In the **Federal Register** of October 25, 2019 (84 FR 57445), in accordance with the amendments to section 510(m)(2) of the FD&C Act, on its own initiative, FDA issued a notice of intent to exempt the identified class II devices from premarket notification requirements under section 510(k) of the FD&C Act, subject to certain limitations. Having received no comments to the docket following a 60-day comment period, FDA is issuing this order to set forth our final determination to exempt the class II devices that were the subject of the notice. Through this action, FDA is now amending the codified language for each identified classification regulation to reflect our final determinations for these class II exemptions.[2]

II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the January 21, 1998, **Federal Register** notice (63 FR 3142) and subsequently in the guidance we issued on February 19, 1998, entitled ''Procedures for Class II Device Exemptions From Premarket Notification, Guidance for Industry and

[1] FDA published the final list under section 510(m)(1)(B) of the FD&C Act in the **Federal Register** of July 11, 2017 (82 FR 31976).

[2] FDA notes that the ''ACTION'' caption for this final order is styled as ''Final amendment; final order,'' rather than ''Final order.'' Beginning in December 2019, this editorial change was made to indicate that the document ''amends'' the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.