

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;

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).

- 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 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 April 21, 2021. This Notification may be amended or rescinded prior to that time, based on circumstances associated with the specific threat.⁸

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

⁸ DHS is working closely with counterparts in Mexico and Canada to identify appropriate public health conditions to safely ease restrictions in the future and support U.S. border communities.

humanitarian reasons or for other purposes in the national interest, permit the processing of travelers to the United States not engaged in “essential travel.”

Alejandro N. Mayorkas,
Secretary, U.S. Department of Homeland Security.

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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 Mexico

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 Mexico into the United States at land ports of entry along the United States-Mexico 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 March 22, 2021 and will remain in effect until 11:59 p.m. EDT on April 21, 2021.

FOR FURTHER INFORMATION CONTACT: Stephanie Watson, Office of Field Operations Coronavirus Coordination Cell, U.S. Customs and Border Protection (CBP) at 202-325-0840.

SUPPLEMENTARY INFORMATION:

Background

On March 24, 2020, DHS published notice of its 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.¹ The document described the developing circumstances regarding the COVID-19

¹ 85 FR 16547 (Mar. 24, 2020). That same day, DHS also published notice of its 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. 85 FR 16548 (Mar. 24, 2020).

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, DHS had determined that the risk of continued transmission and spread of the virus associated with COVID-19 between the United States and Mexico posed a “specific threat to human life or national interests.” DHS later published a series of notifications continuing such limitations on travel until 11:59 p.m. EDT on March 21, 2021.²

DHS continues to monitor and respond to the COVID-19 pandemic. As of the week of March 7, 2021, there have been over 116.1 million confirmed cases globally, with over 2.5 million confirmed deaths.³ There have been over 29.2 million confirmed and probable cases within the United States,⁴ over 881,000 confirmed cases in Canada,⁵ and over 2.1 million 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 Mexico poses an ongoing “specific threat to human life or national interests.”

U.S. and Mexican officials have mutually determined that non-essential travel between the United States and Mexico 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 Mexico, 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.-Mexico 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-Mexico 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 Mexico 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 supporting the movement of cargo between the United States and Mexico);
- 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 Mexico, but does apply to passenger rail, passenger ferry travel, and pleasure boat travel between the United States and Mexico. These restrictions are temporary in nature and shall remain in effect until 11:59 p.m. EDT on April 21, 2021. This Notification may be amended or rescinded prior to that time, based on circumstances associated with the specific threat.⁸

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

² See 86 FR 10816 (Feb. 23, 2021); 86 FR 4967 (Jan. 19, 2021); 85 FR 83433 (Dec. 22, 2020); 85 FR 74604 (Nov. 23, 2020); 85 FR 67275 (Oct. 22, 2020); 85 FR 59669 (Sept. 23, 2020); 85 FR 51633 (Aug. 21, 2020); 85 FR 44183 (July 22, 2020); 85 FR 37745 (June 24, 2020); 85 FR 31057 (May 22, 2020); 85 FR 22353 (Apr. 22, 2020). DHS also published parallel notifications of its decisions to continue temporarily limiting the travel of individuals from Canada into the United States at land ports of entry along the United States-Canada border to “essential travel.” See 86 FR 10815 (Feb. 23, 2021); 86 FR 4969 (Jan. 19, 2021); 85 FR 83432 (Dec. 22, 2020); 85 FR 74603 (Nov. 23, 2020); 85 FR 67276 (Oct. 22, 2020); 85 FR 59670 (Sept. 23, 2020); 85 FR 51634 (Aug. 21, 2020); 85 FR 44185 (July 22, 2020); 85 FR 37744 (June 24, 2020); 85 FR 31050 (May 22, 2020); 85 FR 22352 (Apr. 22, 2020).

³ WHO, Coronavirus disease 2019 (COVID-19) Weekly Epidemiological Update (Mar. 7, 2021), available at <https://www.who.int/publications/m/item/weekly-epidemiological-update---10-march-2021>.

⁴ CDC, COVID Data Tracker (accessed Mar. 15, 2021), https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days.

⁵ WHO, COVID-19 Weekly Epidemiological Update (Mar. 7, 2021).

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).

⁸ DHS is working closely with counterparts in Mexico and Canada to identify appropriate public health conditions to safely ease restrictions in the future and support U.S. border communities.

humanitarian reasons or for other purposes in the national interest, permit the processing of travelers to the United States not engaged in “essential travel.”

Alejandro N. Mayorkas,

Secretary, U.S. Department of Homeland Security.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 524, 529, 556, and 558

[Docket No. FDA-2020-N-0002]

New Animal Drugs; Approval of New Animal Drug Applications; Changes of Sponsorship; Change of Sponsor’s Name and Address

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the animal drug regulations to reflect application-related actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during July, August, and September 2020. FDA is informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable. The animal drug regulations are also being amended to improve the accuracy and readability of the regulations.

DATES: This rule is effective March 19, 2021.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-5689, george.haibel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Approvals

FDA is amending the animal drug regulations to reflect approval actions

for NADAs and ANADAs during July, August, and September 2020, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents may be seen in the office of the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500. Persons with access to the internet may obtain these documents at the CVM FOIA Electronic Reading Room: <https://www.fda.gov/about-fda/center-veterinary-medicine/cvm-foia-electronic-reading-room>. Marketing exclusivity and patent information may be accessed in FDA’s publication, Approved Animal Drug Products Online (Green Book) at: <https://www.fda.gov/animal-veterinary/products/approved-animal-drug-products-green-book>.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAs AND ANADAs APPROVED DURING JULY, AUGUST, AND SEPTEMBER 2020

| Approval date | File No. | Sponsor | Product name | Species | Effect of the action | Public documents |
|----------------------|----------|---|---|--------------------|--|------------------|
| July 9, 2020 | 141-532 | Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940. | BRAVECTO 1-MONTH (furalaner) Chews for Dogs. | Dogs | Original approval for the treatment and prevention of flea infestations, and the treatment and control of tick infestations for 1 month in dogs and puppies. | FOI Summary. |
| July 27, 2020 | 141-538 | Ceva Sante Animale, 10 Avenue de la Ballastière, 33500 Libourne, France. | CARDALIS (spironolactone and benazepril hydrochloride chewable tablets). | Dogs | Original approval with concurrent therapy (e.g., furosemide, etc.) for the management of clinical signs of mild, moderate, or severe congestive heart failure in dogs due to atrioventricular valvular insufficiency (AVVI). | FOI Summary. |
| July 29, 2020 | 200-687 | Cronus Pharma Specialities India Private Ltd., Sy No-99/1, GMR Hyderabad Aviation SEZ Ltd., Mamidipalli Village, Shamshabad Mandal, Ranga Reddy, Hyderabad, Telangana, 501218, India. | Carprofen Chewable Tablets. | Dogs | Original approval as a generic copy of NADA 141-111. | FOI Summary. |
| August 4, 2020 | 200-681 | Dechra Veterinary Products LLC, 7015 College Blvd., Suite 525, Overland Park, KS 66211. | Carprofen Tablets | Dogs | Original approval as a generic copy of NADA 140-035. | FOI Summary. |
| September 9, 2020 | 141-529 | Pharmgate LLC, 1800 Sir Tyler Dr., Wilmington, NC 28405. | MAXIBAN (naracin and nicarbazin) plus PENNITRACIN MD (bacitracin methylenedisalicylate) Type C medicated feeds. | Chickens | Original approval for increased rate of weight gain, improved feed efficiency, and for the prevention of coccidiosis in broiler chickens. | FOI Summary. |
| September 18, 2020. | 200-690 | Pharmasone LLC, 1800 Sir Tyler Dr., Wilmington, NC 28405. | ZOASHIELD 25% (zoalene Type A medicated article). | Chickens, turkeys. | Original approval as a generic copy of NADA 141-218. | FOI Summary. |
| September 28, 2020. | 200-069 | Bimeda Animal Health Ltd., 1B The Herbert Building, The Park, Carrickmines, Dublin 18, Ireland. | OVACYST (gonadorelin) Injectable Solution. | Cattle | Supplemental approval for fixed-time artificial insemination (FTAI) in beef cows and lactating dairy cows. | FOI Summary. |