

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

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).

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 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 March 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

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.

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.”

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 Standard Time on February 22, 2021 and will remain in effect until 11:59 p.m. Eastern Daylight Time (EDT) on March 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, the Department of Homeland Security (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 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. EST on February 21, 2021.²

DHS continues to monitor and respond to the COVID-19 pandemic. As of the week of February 14, 2021, there have been over 108.2 million confirmed cases globally, with over 2.3 million confirmed deaths.³ There have been over 27.6 million confirmed and probable cases within the United States,⁴ over 820,000 confirmed cases in Canada,⁵ and over 1.9 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.

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).

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 March 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

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.

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).

² *See* 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 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 (Feb. 16, 2021), available at <https://www.who.int/publications/m/item/weekly-epidemiological-update---16-february-2021>.

⁴ CDC, COVID Data Tracker (accessed Feb. 18, 2021), available at <https://covid.cdc.gov/covid-data-tracker/>.

⁵ WHO, COVID-19 Weekly Epidemiological Update (Feb. 16, 2021).

⁶ *Id.*

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.”

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, and 522

[Docket No. FDA-2019-N-5405]

New Animal Drug Applications; Beta-Aminopropionitrile Fumarate; n-Butyl Chloride; Cupric Glycinate Injection; Dichlorophene and Toluene; Orgotein for Injection; Tetracycline Tablets

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule, technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the withdrawal of approval of seven new animal drug applications (NADAs) for lack of compliance with the reporting requirements in an FDA regulation.

DATES: This rule is effective February 23, 2021.

FOR FURTHER INFORMATION CONTACT: David Alterman, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-5720, david.alterman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Elsewhere in this issue of the **Federal Register**, FDA gave notice that approval of the seven NADAs listed in table 1, and all supplements and amendments thereto, is withdrawn, effective February 23, 2021, for lack of compliance with reporting requirements in 21 CFR 514.80. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect withdrawal of approval of the following applications and a current format. Withdrawal of approval of NADA 065-067 for Tetracycline Hydrochloride (HCl) Tablets did not require amending the regulations.

TABLE 1—NADAS FOR WHICH APPROVAL IS WITHDRAWN

Application No.	Trade name (drug)	Sponsor	21 CFR section
031-971	CUPRATE (cupric glycinate)	Walco International, Inc., 15 West Putnam, Porterville, CA 93257.	522.518
045-863	PALOSEIN (orgotein)	OXIS International, Inc., 6040 N Cutter Circle, Suite 317, Portland, OR 97217-3935.	522.1620
046-922	SERGEANTS SURE SHOT (n-butyl chloride) Capsules.	ConAgra Pet Products Co., 3902 Leavenworth St., Omaha, NE 68105.	520.260
046-923	SERGEANTS (n-butyl chloride) Puppy Worm Capsules.	ConAgra Pet Products Co., 3902 Leavenworth St., Omaha, NE 68105.	520.260
065-067	Tetracycline HCl Tablets	Premo Pharmaceutical Laboratories, Inc., 111 Leuning St., South Hackensack, NJ 07606.	Not codified
140-850	ELITE (dichlorophene and toluene) Dog and Cat Wormer.	RSR Laboratories, Inc., 501 Fifth St., Bristol, TN 37620.	520.580
141-107	BAPTEN for Injection (β-aminopropionitrile fumarate).	Alaco, Inc., 1500 North Wilmot Rd., Suite 290-C, Tucson, AZ 85712.	522.84

Following these withdrawals of approval, Alaco, Inc.; ConAgra Pet Products Co.; OXIS International, Inc.; RSR Laboratories, Inc.; and Walco International, Inc., are no longer the sponsors of an approved application. Accordingly, 21 CFR 510.600(c) is being amended to remove the entries for these firms.

II. Legal Authority

This rule sets forth technical amendments to the regulations to codify recent actions on approved new animal drug applications and corrections to improve the accuracy of the regulations, and as such does not impose any burden on regulated entities. This rule is issued under section 512(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b(i)), which requires

Federal Register publication of the conditions of use of an approved or conditionally approved new animal drug and the name and address of the drug’s sponsor in a “notice, which upon publication shall be effective as a regulation.” A notice published pursuant to section 512(i) is not subject to the notice-and-comment rulemaking requirements of the Administrative Procedure Act, 5 U.S.C. 551 *et seq.* See section 512(i) of the FD&C Act (21 U.S.C. 360b(i)); 21 CFR 10.40(e)(3); S. Rep. 90-1308, at 5 (1968).

This document does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a “rule of particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

Likewise, this is not a rule subject to Executive Order 12866, which defines a rule as “an agency statement of general applicability and future effect, which the agency intends to have the force and effect of law, that is designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency.”

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 520 and 522

Animal drugs.