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 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 September 21, 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. 2020–18470 Filed 8–19–20; 4:15 pm]

BILLING CODE 9112–FP–P

[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).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 610

[Docket No. FDA–2018–N–4757]

RIN 0910–AH95

Revocation of the Test for Mycoplasma

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing a final rule to remove the specified test for the presence of *Mycoplasma* for live virus vaccines and inactivated virus vaccines produced from in vitro living cell cultures. The rule is being finalized because the existing test for *Mycoplasma* is overly restrictive in that it identifies only one test method in detail to be used even though other methods also may be appropriate. More sensitive and specific methods exist and are currently being practiced, and removal of the specific method to test for *Mycoplasma* provides flexibility for accommodating new and evolving technology and capabilities without diminishing public health protections. This action is part of FDA's implementation of Executive Orders under which FDA is comprehensively reviewing existing regulations to identify opportunities for repeal, replacement, or modification that will result in meaningful burden reduction, while allowing the Agency to achieve our public health mission and fulfill statutory obligations.

DATES: This rule is effective September 21, 2020.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the ''Search'' box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Tami Belouin, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose of the Final Rule

FDA is removing the regulation requiring a specified test for the presence of *Mycoplasma* for live virus vaccines produced from in vitro living cell cultures and inactivated virus vaccines produced from such living cell cultures because the regulation is overly restrictive in that it identifies only one test method in detail to be used even though other methods also may be appropriate. More sensitive and specific methods exist and are currently being practiced, and removal of the required test for *Mycoplasma* provides flexibility for accommodating new and evolving technology and capabilities without diminishing public health protections.

B. Summary of the Major Provisions of the Final Rule

The final rule removes § 610.30 (21 CFR 610.30), which details the method for *Mycoplasma* testing of samples of the virus harvest pool and control fluid pool of live virus vaccines and inactivated virus vaccines produced from in vitro living cell cultures.

C. Legal Authority

FDA is taking this action under the biological products provisions of the Public Health Service Act (the PHS Act), and the drugs and general administrative provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

D. Costs and Benefits

Because this final rule will not impose any additional regulatory burdens, this regulation is not anticipated to result in any compliance costs and the economic impact is expected to be minimal.

II. Background

A. Introduction

On February 24, 2017, Executive Order 13777, ''Enforcing the Regulatory Reform Agenda'' (*https://www.federalregister.gov/documents/2017/03/01/2017-04107/enforcing-the-regulatory-reform-agenda;* 82 FR 12285, March 1, 2017) was issued. One of the provisions in the Executive Order requires Agencies to evaluate existing regulations and make recommendations to the Agency head regarding their repeal, replacement, or modification, consistent with applicable law. As part of this initiative, FDA is revoking a regulation as specified in this final rule.

B. Need for the Regulation

It has become increasingly clear that the requirement specifying a test for *Mycoplasma* is too restrictive for live virus vaccines and inactivated virus vaccines produced from in vitro living cell cultures because they specify particular methodologies when alternatives may be available that provide the same or greater level of assurance of safety. Modifications to *Mycoplasma* testing described in § 610.30 must meet the requirements of 21 CFR 610.9.

Thus, the Agency believes that the regulation may no longer reflect the current testing procedures as a general matter and that it is more appropriate, flexible, and efficient to identify appropriate testing requirements for particular products in the biologics license application (BLA).

This final rule removes the specified test for the presence of *Mycoplasma* to provide flexibility for accommodating new and evolving technology and capabilities without diminishing public health protections. Removal of this regulation allows manufacturers of live virus vaccines produced from in vitro living cell cultures and inactivated virus vaccines produced from such living cell cultures to select the most scientifically appropriate *Mycoplasma* testing method to assure the safety, purity, and potency of their vaccines.

These newer technologies can result in higher sensitivity and specificity of *Mycoplasma* detection and could reduce the time required to complete testing for *Mycoplasma.* Removal of this regulation does not remove *Mycoplasma* testing requirements specified in individual BLAs. A manufacturer of a live virus vaccine produced from in vitro living cell cultures and inactivated virus vaccines produced from such living cell cultures will continue to be required to follow the *Mycoplasma* test requirements specified in its BLA, unless the BLA was revised to modify or replace the test through a supplement in accordance with § 601.12(c) (21 CFR 601.12(c)). FDA would review proposed changes to a manufacturer's approved biologics license in the context of that particular application to ensure that any such action is appropriate.

Although the final rule removes the regulation, a manufacturer continues to be required to test for *Mycoplasma* as specified in its BLA. This action provides regulated industry with flexibility, as appropriate, to employ advances in science and technology as they become available, without diminishing public health protections. As appropriate, the Agency will describe the appropriate tests for particular products in manufacturers' BLAs.

C. Summary of Comments to the Proposed Rule

We received comments on the proposed rule from individuals and industry submitters. The comments were generally supportive, with some comments suggesting new testing procedures be proposed. These comments are further summarized in section IV.

III. Legal Authority

We are issuing this final rule under the biological products provisions of the PHS Act (42 U.S.C. 216, 262, 263, 263a, and 264) and the drugs and general administrative provisions of the FD&C Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360c, 360d, 360h, 360i, 371, 372, 374, and 381). Under these provisions of the PHS Act and the FD&C Act, we have the authority to issue and enforce regulations designed to ensure that biological products are safe, pure, and potent, and prevent the

introduction, transmission, and spread of communicable disease.

IV. Comments on the Proposed Rule and FDA Response

A. Introduction

We received comments on the proposed rule from individuals and industry submitters. We describe and respond to the comments in section IV.B. We have combined comments on similar topics and have numbered each comment to help distinguish between different comments. The number assigned to each comment or comment topic is purely for organizational purposes and does not signify the comment's value or importance or the order in which comments were received.

B. Comments and FDA Response

(Comment 1) One comment requested that FDA not finalize the rule, but instead amend the proposal to revoke the current test for *Mycoplasma.* The commenter proposed that FDA include methodologies on newer tests and how they are distinguishable from the present test; comparable data on the accuracy of *Mycoplasma* detection between the present and newer tests, and any other additional information that would support FDA's argument that the newer tests are more efficient.

(Response 1) FDA interprets this comment to support the proposal to remove the currently described methodology and to amend the regulation to specify alternative acceptable tests. The purpose of this rulemaking is to permit manufacturers of live virus vaccines produced from in vitro living cell cultures and inactivated virus vaccines produced from such living cell cultures to select the most scientifically appropriate *Mycoplasma* testing method to assure the safety, purity, and potency of their vaccines. Thus, FDA declines to amend the regulation to specify alternative acceptable tests because this would not achieve the goal of allowing flexibility, as appropriate, to employ advances in science and technology as they become available without diminishing public health protections. However, FDA acknowledges that guidance is helpful to describe FDA's current thinking on alternative methods of testing for *Mycoplasma* in manufacturing samples of live virus vaccines and inactivated virus vaccines produced from in vitro living cell cultures. FDA notes that recommended alternative methods for *Mycoplasma* testing for viral vaccines are described in ''Guidance for Industry: Characterization and Qualification of Cell Substrates and Other Biological Materials Used in the Production of Viral Vaccines for Infectious Disease Indications'' (February 2010) (*https://www.fda.gov/media/78428/download*).

(Comment 2) One comment supported the proposed rule.

(Response 2) We acknowledge and appreciate the supportive comment.

(Comment 3) One comment did not comment specifically on finalizing the rule, but stated that with changes to technology, it makes sense to update testing procedures. The comment stated that ''a list of the new proposed test methods would be beneficial to compare the overall benefits and disadvantages.'' Another comment suggested that if the rule is finalized, FDA should provide guidance for alternative methods of testing for *Mycoplasma.*

(Response 3) While the comment states that it would be helpful to have a list of new proposed test methods, FDA does not believe the regulation should be amended to include such a list because that list could become outdated. License holders are welcome to discuss with FDA proposals to change their existing test methods and to submit proposals to FDA to revise the current test methods in use.

FDA also acknowledges that guidance is helpful to describe FDA's current thinking on acceptable alternative methods of testing for *Mycoplasma* in manufacturing samples of live virus vaccines and inactivated virus vaccines produced from in vitro living cell cultures. FDA notes that recommended alternative methods for *Mycoplasma* testing for viral vaccines are described in ''Guidance for Industry: Characterization and Qualification of Cell Substrates and Other Biological Materials Used in the Production of Viral Vaccines for Infectious Disease Indications'' (February 2010) (*https://www.fda.gov/media/78428/download*).

(Comment 4) One comment strongly supported removal of the regulation and agreed that more sensitive test methods exist; however, the commenter wanted the scope of the impact to be expanded to include all biological product manufacturers.

(Response 4) We acknowledge and appreciate the supportive comment. The request to expand the revocation to include all biological product manufacturers is beyond the scope of this rule making because § 610.30 pertains to manufacturers of live virus vaccines and inactivated virus vaccines produced from in vitro living cell cultures.

V. Effective Date

The final rule will become effective 30 days after the date of publication in the **Federal Register**.

VI. Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 13771 requires that the costs associated with significant new regulations ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' We believe that this final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule would increase flexibility and does not add any new regulatory responsibilities, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $154 million, using the most current (2018) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Costs and Benefits

This final rule will amend the biologics regulations under § 610.30 by removing the specified test for *Mycoplasma* in the production of live virus vaccines produced from in vitro living cell cultures and inactivated virus

vaccines produced from such living cell cultures.

Removing the § 610.30 Test for *Mycoplasma* will provide manufacturers with the flexibility to determine the most appropriate and effective *Mycoplasma* testing methods. FDA guidance dated after § 610.30, codified in 1973 (November 20, 1973, 38 FR 32056), outlines up-to-date scientific practices to identify *Mycoplasma* in production of live virus vaccines produced from in vitro living cell cultures and inactivated virus vaccines produced from in vitro living cell cultures. In practice, a vaccine manufacturer can change its procedures at any time with submission and prior approval of a supplement to its BLA. As a result, we do not expect the repeal of the § 610.30 Test for Mycoplasma to significantly influence the behavior or procedures of vaccine manufacturers.

Because manufacturers already have the ability to pursue alternative testing procedures, we anticipate no measurable change in industry or FDA behavior from this final rulemaking. We therefore expect the elimination of the § 610.30 Test for *Mycoplasma* to be cost neutral. This final rule will therefore produce no quantifiable savings, costs, or transfers. We also expect no public health benefits to be lost as a result of this revocation. Finally, we note that this final rulemaking may drive some manufacturers to streamline their procedures and search for more efficient *Mycoplasma* testing methods. This optimization may produce some unquantifiable efficiencies.

TABLE 1—SUMMARY OF BENEFITS, COSTS AND DISTRIBUTIONAL EFFECTS OF FINAL RULE

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered	
Benefits:							
Annualized					7		
Monetized $millions/year					3		
Annualized					7		
Quantified					3		
Qualitative	Benefits to manufacturers from flexibility to determine appropriate and effective *Mycoplasma* testing methods.						
Costs:							
Annualized					7		
Monetized $millions/year					3		
Annualized					7		
Quantified					3		
Qualitative	Costs to manufacturers to change *Mycoplasma* testing methods, if voluntarily pursued.						
Transfers:							
Federal					7		
Annualized					3		
Monetized $millions/year							
From/To	From:			To:			
Other					7		
Annualized					3		
Monetized $millions/year							
From/To	From:			To:			

Effects:
State, Local or Tribal Government: None.
Small Business: None.
Wages: None.
Growth: None.

In line with Executive Order 13771, in table 2 we present annualized values of costs and cost savings over an infinite time horizon. There are no quantifiable costs or cost savings from this rule. This final rule would be considered a deregulatory action under Executive Order 13771.

TABLE 2—EXECUTIVE ORDER 13771 SUMMARY TABLE

[in $ Millions 2016 Dollars, Over an Infinite Time Horizon]

Item	Primary estimate (7%)	Lower estimate (7%)	Upper estimate (7%)
Present Value of Costs			
Present Value of Cost Savings			
Present Value of Net Costs			
Annualized Costs			
Annualized Cost Savings			
Annualized Net Costs			

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. The full analysis of economic impacts is available in the docket for this final rule (Ref. 1) and at *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations*.

VII. Analysis of Environmental Impact

We have determined under 21 CFR 25.31(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

IX. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. We have determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

X. Consultation and Coordination With Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive Order and, consequently, a tribal summary impact statement is not required.

XI. Reference

The following reference is on display at the Dockets Management Staff (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m. Monday through Friday; it is also available electronically at *https://www.regulations.gov*. FDA has verified the website address, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. FDA/Economics Staff, ''Elimination of the 21 CFR 610.30 Test for *Mycoplasma* Preliminary Regulatory Impact Analysis, Preliminary Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis,'' 2018. (Available at *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations*.)

List of Subjects in 21 CFR part 610

Biologics, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 610 is amended as follows:

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

■ 1. The authority citation for part 610 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360c, 360d, 360h, 360i, 371, 372, 374, 381; 42 U.S.C. 216, 262, 263, 263a, 264.

Subpart D—[Removed and Reserved]

■ 2. Remove and reserve subpart D, consisting of § 610.30.

Dated: July 29, 2020.

Stephen M. Hahn,

Commissioner of Food and Drugs.

[FR Doc. 2020–17085 Filed 8–20–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1308 and 1312

[Docket No. DEA–500]

RIN 1117–AB53

Implementation of the Agriculture Improvement Act of 2018

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Interim final rule with request for comments.

SUMMARY: The purpose of this interim final rule is to codify in the Drug Enforcement Administration (DEA) regulations the statutory amendments to the Controlled Substances Act (CSA) made by the Agriculture Improvement Act of 2018 (AIA), regarding the scope of regulatory controls over marihuana, tetrahydrocannabinols, and other marihuana-related constituents. This interim final rule merely conforms DEA's regulations to the statutory amendments to the CSA that have already taken effect, and it does not add additional requirements to the regulations.

DATES: Effective August 21, 2020. Electronic comments must be submitted, and written comments must be postmarked, on or before October 20, 2020. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference ''RIN 1117–AB53/Docket No. DEA–500'' on all correspondence, including any attachments.