information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Lyndsay Hennessey, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–7605.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Importation of Prescription Drugs Final Rule Questions and Answers.'' We are issuing this guidance in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104–121, as amended by Pub. L. 110–28) to help small entities better understand and comply with the final rule, ''Importation of Prescription Drugs,'' published in the **Federal Register** of October 1, 2020 (85 FR 62094). The final rule will implement section 804(b) through (h) of the FD&C Act (21 U.S.C. 384(b) through (h)) to allow importation of certain prescription drugs from Canada. The final rule, which is codified in 21 CFR parts 1 and 251, became effective November 30, 2020.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115(c)(2)). The guidance represents the current thinking of FDA on Importation of Prescription Drugs Final Rule Questions and Answers. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 251 have been approved under OMB control number 0910–0888.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs*, *https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: May 19, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–11276 Filed 5–25–22; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2021–0472; FRL–9646–02–R4]

Air Plan Approval; North Carolina; Repeal of Delegation Authority

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a State Implementation Plan (SIP) revision submitted by the State of North Carolina's Department of Environmental Quality (DEQ), Division of Air Quality (DAQ or Division), via a letter dated April 13, 2021. This rulemaking addresses the repeal of a State regulation related to delegation of authority and removal of the regulation from the North Carolina SIP. EPA is finalizing approval of these changes pursuant to the Clean Air Act (CAA or Act).

DATES: This rule is effective June 27, 2022.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R04–OAR–2021–0472. All documents in the docket are listed on the *www.regulations.gov* website. Although listed in the index, some information may not be publicly available, *i.e.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Andres Febres, Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960.

The telephone number is (404) 562–8966. Mr. Febres can also be reached via electronic mail at *febres-martinez.andres@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On April 13, 2021, the State of North Carolina submitted changes to the North Carolina SIP for EPA's approval.[1] Through this final rulemaking, EPA is approving changes to the North Carolina SIP related to 15A North Carolina Administrative Code (NCAC) Subchapter 02D, Rule .0615, *Delegation*.[2] The April 13, 2021, SIP revision removes the aforementioned regulation from the SIP because the regulation is unnecessary and has been repealed at the state level.

Through a Notice of Proposed Rulemaking (NPRM), EPA proposed to approve these changes on March 31, 2022. *See* 87 FR 18759. More details on North Carolina's April 13, 2021, submission and EPA's rationale for approving the aforementioned changes can be found in the March 31, 2022, NPRM. Comments on the NPRM were due on or before May 2, 2022. No comments were received on the March 31, 2022, NPRM.

II. Incorporation by Reference

In this document, EPA is finalizing regulatory text that includes incorporation by reference. Specifically, EPA is finalizing the removal of 15A NCAC 02D, Rule .0615, *Delegation,* from the North Carolina State Implementation Plan, which is incorporated by reference in accordance with the requirements of 1 CFR part 51. EPA has made and will continue to make the SIP generally available at the EPA Region 4 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

III. Final Action

EPA is finalizing the approval of changes to the North Carolina SIP. Specifically, for the reasons described in the March 31, 2022, NPRM, EPA is finalizing the removal of 15 NCAC 02D, Rule .0615, *Delegation,* from the North Carolina SIP.

[1] EPA received the submittal on April 14, 2021, and for clarity, refers to the submission per its ''letter date'' of April 13, 2021, throughout this notice.

[2] EPA notes that the Agency received several revisions to the North Carolina SIP that were transmitted with the same April 13, 2021, cover letter. EPA will be considering action for these other SIP revisions in separate rulemakings.

IV. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. *See* 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. This action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by July 25, 2022. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. *See* section 307(b)(2).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: May 20, 2022.

Daniel Blackman,

Regional Administrator, Region 4.

For the reasons stated in the preamble, the EPA amends 40 CFR part 52 as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart II—North Carolina

§ 52.1770 [Amended]

■ 2. In § 52.1770(c), amend Table (1) ''EPA Approved North Carolina Regulations'' by removing the entry for ''Section .0615.''

[FR Doc. 2022–11290 Filed 5–25–22; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 212, 225, and 252

[Docket DARS–2020–0031]

RIN 0750–AK97

Defense Federal Acquisition Regulation Supplement: Prohibition on Contracting With Persons That Have Business Operations With the Maduro Regime (DFARS Case 2020–D010)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a statute that prohibits DoD from entering into contracts for the procurement of goods and services with any person that has business operations with an authority of the government of Venezuela that is not recognized as the legitimate government of Venezuela by the United States Government.

DATES: Effective May 26, 2022.

FOR FURTHER INFORMATION CONTACT: Kimberly Bass, telephone 571–372–6174.

SUPPLEMENTARY INFORMATION:

I. Background

DoD published a proposed rule in the **Federal Register** at 85 FR 53751 on August 31, 2020, to implement section 890 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2020 (Pub. L. 116–92). Section 890 prohibits contracts for the procurement of goods and services with any person that has business operations with an authority of the government of Venezuela, subject to exceptions. Six respondents submitted public comments in response to the proposed rule.

II. Discussion and Analysis

DoD reviewed the public comments in the development of the final rule. A discussion of the comments and the changes made to the rule as a result of those comments is provided, as follows:

A. Summary of Significant Changes From the Proposed Rule

To further clarify and to eliminate any ambiguity, the solicitation provision 252.225–7055, Representation Regarding Business Operations with the Maduro Regime, was revised to clarify that ''. . . by submission of its offer, the Offeror represents that the Offeror is a person that—(1) Does not have any business operations with an authority of the Maduro regime or the government of Venezuela that is not recognized as the legitimate government of Venezuela by the U.S. Government; or . . .''. The contract clause 252.225–7056, Prohibition Regarding Business Operations with the Maduro Regime, applies to the entity that was awarded the contract. Therefore, no change was made to the clause.

Additional revisions were made to the text and clause number designations to accommodate updated numerical designations required in the final rule. In addition, a revision was made to 225.7020–4, Joint Determination, to explicitly state that delegation authority is to remain at the level of Secretary of Defense and Secretary of State without power of redelegation.

B. Analysis of Public Comments

1. Support for the Rule

Comment: Several respondents provided overall support of the rule. A respondent expressed support for the rule because it is an effectual way to limit the Maduro regime's access to American made or American preferred military technology. The respondent also expressed support for the exceptions for humanitarian aid. Another respondent supported the rule overall because limiting contracts is a push in opposition of the Maduro regime. A respondent commended the rule and hopes this is not a final step in solving unrest in Venezuela.

Response: DoD acknowledges the respondents' support for the rule.

2. Joint Determination

Comment: A respondent expressed concern that requiring a joint determination of both the Secretary of Defense and the Secretary of State that the restriction does not apply to certain acquisitions may limit the relief that can be provided to the people of Venezuela. Another respondent expressed similar concern with the high level of approval necessary for the joint determination and also expressed concern with the process for making the joint determination. A respondent included a list of proposed factors to consider in whether to seek a joint determination. A respondent further stated that there were no procedures or guidance on the Government determination process.

Response: The proposed rule implements section 890 of the NDAA for FY 2020. Section 890 prohibits DoD from entering into a contract for the procurement of goods or services with any person that has business operations with an authority of the government of Venezuela that is not recognized as the legitimate government of Venezuela by the United States Government. Section 890 does not apply the prohibition to acquisitions where the Secretary of Defense and Secretary of State have jointly determined that the acquisition is necessary for providing humanitarian assistance, disaster relief, or urgent lifesaving measures to the people of Venezuela; carrying out noncombatant evacuations; or is otherwise vital to U.S. national security interests. The process of the joint determination is in accordance with internal Government operating procedures. The rule's implementation is consistent with the statutory requirements of section 890 and does not allow for further delegation of the authority for the joint determination. Thus, the final rule implements the authority for the joint determination at the level of the Secretary of Defense and Secretary of State.

3. National Security Waiver

Comment: A couple of respondents provided questions relating to the lack of guidelines for securing a national security interest exception in the proposed rule.

Response: The final rule is directly aligned with the statutory language and implements section 890 of the NDAA for FY 2020. The reference to national security interests appears in section 890(b)(1)(A) and was implemented accordingly in DFARS 225.7020–4(a)(2) of the final rule.

4. Definitions

Comment: A respondent stated that the definition of ''person'' is overly broad and could adversely affect contracts held by businesses that have no operations in, or connections with, Venezuela. Another respondent further stated that in light of the broad definition of ''person'' and ''business operations'' in the rule, there is a lack of clarity in the solicitation provision 252.225–7055 as to whether an ''offeror'' who certifies that it does not have any business operations with an authority of