TSR: Yes, except for exports and reexports to destinations outside of those countries listed in Country Group A:5 (See Supplement No. 1 to part 740 of the EAR) of ''software'' controlled by 5D001.a and ''specially designed'' for items controlled by 5A001.b.5 and 5A001.h, and N/A for ''software'' classified under ECCN 5D001.a (for 5A001.j) or 5D001.c (for 5A001.j or 5B001.a (for 5A001.j)).

ACE: Yes for 5D001.a (for 5A001.j) and 5D001.c (for 5A001.j or 5B001.a (for 5A001.j)), except to Country Group E:1 or E:2. See § 740.22 of the EAR for eligibility criteria.

Special Conditions for STA

STA: License Exception STA may not be used to ship or transmit 5D001.a ''software'' ''specially designed'' for the ''development'' or ''production'' of equipment, functions or features, specified by ECCN 5D001.a (for 5A001.j) and 5D001.c (for 5A001.j or 5B001.a (for 5A001.j)) to any of the destinations listed in Country Group A:5 or A:6 (See Supplement No.1 to part 740 of the EAR); 5A001.b.3, .b.5 or .h; and for 5D001.b. for ''software'' ''specially designed'' or modified to support ''technology'' specified by the STA paragraph in the License Exception section of ECCN 5E001 to any of the destinations listed in Country Group A:6.

List of Items Controlled

Related Controls: See also 5D980 and 5D991.
Related Definitions: N/A
Items:

a. ''Software'' ''specially designed'' or modified for the ''development'', ''production'' or ''use'' of equipment, functions or features controlled by 5A001;

b. [Reserved]

c. Specific ''software'' ''specially designed'' or modified to provide characteristics, functions or features of equipment, controlled by 5A001 or 5B001;

d. ''Software'' ''specially designed'' or modified for the ''development'' of any of the following telecommunication transmission or switching equipment:

d.1. [Reserved]

d.2. Equipment employing a ''laser'' and having any of the following:

d.2.a. A transmission wavelength exceeding 1,750 nm; *or*

d.2.b. Employing analog techniques and having a bandwidth exceeding 2.5 GHz; *or*

Note: *5D001.d.2.b does not control ''software'' ''specially designed'' or modified for the ''development'' of commercial TV systems.*

d.3. [Reserved]

d.4. Radio equipment employing Quadrature-Amplitude-Modulation (QAM) techniques above level 1,024.

e. ''Software'', other than that specified by 5D001.a or 5D001.c, ''specially designed'' or modified for monitoring or analysis by law enforcement, providing all of the following:

e.1. Execution of searches on the basis of ''hard selectors'' of either the content of communication or metadata acquired from a communications service provider using a 'handover interface'; *and*

Technical Notes:

1. For the purposes of 5D001.e, a 'handover interface' is a physical and logical interface, designed for use by an authorised law enforcement authority, across which targeted interception measures are requested from a communications service provider and the results of interception are delivered from a communications service provider to the requesting authority. The 'handover interface' is implemented within systems or equipment (*e.g.,* mediation devices) that receive and validate the interception request, and deliver to the requesting authority only the results of interception that fulfil the validated request.

2. 'Handover interfaces' may be specified by international standards (including but not limited to ETSI TS 101 331, ETSI TS 101 671, 3GPP TS 33.108) or national equivalents.

e.2. Mapping of the relational network or tracking the movement of targeted individuals based on the results of searches on content of communication or metadata or searches as described in 5D001.e.1.

Note: *5D001.e does not apply to ''software'' ''specially designed'' or modified for any of the following:*

a. Billing purposes;
b. Network Quality of Service (QoS);
c. Quality of Experience (QoE);
d. Mediation devices; or
e. Mobile payment or banking use.

* * * * *

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 2022–11282 Filed 5–25–22; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 251

[Docket No. FDA–2021–D–0958]

Importation of Prescription Drugs Final Rule Questions and Answers; Guidance for Industry: Small Entity Compliance Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance for industry entitled ''Importation of Prescription Drugs Final Rule Questions and Answers.'' The guidance is intended to help small entities comply with the final rule entitled ''Importation of Prescription Drugs.'' The final rule was issued to implement a provision of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to allow importation of certain prescription drugs from Canada.

DATES: The announcement of the guidance is published in the **Federal Register** on May 26, 2022.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'''' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2021–D–0958 for ''Importation of Prescription Drugs Final Rule Questions and Answers.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential

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.