DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1100, 1107, 1114, 1140, and 1143

[Docket No. FDA–2022–N–3262]

Definition of the Term ''Tobacco Product'' in Regulations Issued Under the Federal Food, Drug, and Cosmetic Act

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

ACTION: Technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is announcing conforming changes to its regulations issued under the Federal Food, Drug, and Cosmetic Act (FD&C Act) as required by the Consolidated Appropriations Act of 2022, which amended the term ''tobacco product'' in the FD&C Act to include products that contain nicotine from any source.

DATES: The technical amendments to title 21 of the Code of Federal Regulations (CFR) are effective March 20, 2023.

FOR FURTHER INFORMATION CONTACT: Paul Hart or Laura Chilaka, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993, 877–287–1373, *AskCTP@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) was enacted on June 22, 2009, amending the FD&C Act and providing FDA with the authority to regulate tobacco products. Section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)), as amended by the Tobacco Control Act, defined the term ''tobacco product'' to mean any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). It further stated that the term ''tobacco product'' does not mean an article that is a drug under section 201(g)(1), a device under section 201(h), or a combination product described in section 503(g) of the FD&C Act (21 U.S.C. 353(g)).

The Consolidated Appropriations Act of 2022 (the Appropriations Act) (Pub. L. 117–103), enacted on March 15, 2022, amended the definition of the term ''tobacco product'' in section 201(rr) of the FD&C Act to include products that contain nicotine from any source. It further amended the definition to exclude articles that are foods under section 201(f) of the FD&C Act if such articles contain no nicotine or no more than trace amounts of naturally occurring nicotine. The Appropriations Act also amended section 901(b) of the FD&C Act (21 U.S.C. 387a(b)), which concerns FDA authority over tobacco products, by adding a sentence stating chapter IX of the FD&C Act shall also apply to any tobacco product containing nicotine that is not made or derived from tobacco. As a result, tobacco products that contain non-tobacco nicotine (NTN), including synthetic nicotine, are now subject to the provisions in chapter IX of the FD&C Act (21 U.S.C. 387 to 387t), including, but not limited to the:

- Adulteration and misbranding provisions (sections 902 and 903 of the FD&C Act);
- Required submission of ingredient listing and reporting of harmful and potentially harmful constituents for all tobacco products (section 904 of the FD&C Act);
- Required establishment registration and product listing (section 905 of the FD&C Act);
- Prohibition of selling tobacco products to individuals under 21 years of age (section 906(d)(5) of the FD&C Act);
- Requirement that new tobacco products have an FDA marketing order (section 910 of the FD&C Act) in effect; and
- Requirement that modified risk tobacco products have a modified risk order in effect (section 911 of the FD&C Act).

The Appropriations Act further states that products that are tobacco products under the amended definition in section 201(rr) of the FD&C Act shall be subject to all requirements of regulations for tobacco products and specifies that the term ''tobacco product'' in regulations and guidance issued, in whole or in part, under the FD&C Act shall have the meaning of, and shall be deemed amended to reflect the meaning of, the amended definition in section 201(rr). As a result, beginning April 14, 2022, tobacco products that contain NTN, including synthetic nicotine, are subject to the provisions that apply to tobacco products in FDA's regulations, including, but not limited to:

- Refuse to accept criteria for premarket submissions (21 CFR 1105.10);
- Content and format requirements for premarket tobacco product applications (21 CFR part 1114);
- Exemption from substantial equivalence requirements (21 CFR part 1107, subpart A); and
- Prohibition of the distribution of free samples (21 CFR 1140.16(d)).

The Appropriations Act directs FDA to publish a notice in the **Federal Register** to update the Code of Federal Regulations (CFR) to reflect the deemed amendment to existing regulations and guidance. Accordingly, we are making conforming changes to the CFR to reflect the statutory amendments made by the Appropriations Act to tobacco product regulations issued in whole or in part under the FD&C Act.[1] Elsewhere in this edition of the **Federal Register**, we are issuing a notice to announce conforming changes to the definition of tobacco product in guidances issued in whole or in part under the FD&C Act.

II. Description of Changes to FDA Regulations

FDA is updating the definition of ''tobacco product'' in regulations issued, in whole or in part, under the FD&C Act, to reflect the amendments made by the Appropriations Act. The definition of ''tobacco product,'' where included in the text of FDA regulations, is being updated to reflect the statutory amendments by adding the phrase ''or containing nicotine from any source'' after the words ''from tobacco,'' and incorporating the exclusion of articles that are foods as defined in section 201(f) of the FD&C Act if such articles contain no nicotine or no more than trace amounts of naturally occurring nicotine. The definition of ''tobacco product'' is being updated in the following sections of the CFR:

[1] The Office of the Federal Register (OFR) has published this document under the category ''Rules and Regulations'' with an action heading of ''technical amendment'' pursuant to its interpretation of 1 CFR 5.9(b). We note that the categorization as such for purposes of publication in the **Federal Register** does not affect the legal content or intent of the document. See, 1 CFR 5.1(c).

TABLE 1—UPDATED REGULATIONS

21 CFR section (part/heading)	OMB control No. (if applicable) [2]
1100.3 (Part 1100—General)	N/A.
1100.202 (Part 1100—Subpart C—Maintenance of Records Demonstrating that a Tobacco Product was Commercially Marketed in the United States as of February 15, 2007).	0910–0775.
1107.12 (Part 1107—Exemption Requests and Substantial Equivalence Reports)	0910–0684 and 0910–0673.
1114.3 (Part 1114—Premarket Tobacco Product Applications)	0910–0879.
1140.3 (Part 1140—Cigarettes, Smokeless Tobacco, and Covered Tobacco Products)	N/A.
1143.1 (Part 1143—Minimum Required Warning Statements)	0910–0768.

FDA is also revising 21 CFR 1100.1 and 1100.2 by adding the phrase ''any tobacco product containing nicotine not made or derived from tobacco'' to the list of tobacco products subject to chapter IX of the FD&C Act without needing to be deemed by regulation. These changes simply reflect amendments made by the Appropriations Act to section 901(b) of the FD&C Act.

III. Paperwork Reduction Act of 1995

The amendments made by the Appropriations Act result in changes to some previously approved collections of information that are subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The OMB control numbers for these information collections are listed in table 1. FDA has published, and intends to continue publishing, notices concerning proposed changes to the relevant information collection activities in other editions of the **Federal Register**. In addition, in compliance with the PRA, we will submit revisions to the current information collections to OMB for review.

List of Subjects

21 CFR Parts 1100, 1107, and 1114

Administrative practice and procedure, Cigars and cigarettes, Smoking, Tobacco.

21 CFR Part 1140

Advertising, Labeling, Smoking, Tobacco.

21 CFR Part 1143

Advertising, Labeling, Packaging and containers, Smoking, Tobacco.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 1100, 1107, 1114, 1140, and 1143 are amended as follows:

PART 1100—GENERAL

■ 1. The authority citation for part 1100 is revised to read as follows:

Authority: 21 U.S.C. 371, 374, 387a(b), 387e, 387i; Pub. L. 117–103, 136 Stat. 49.

■ 2. Add a heading for subpart A before § 1100.1 to read as follows:

Subpart A—Tobacco Products Subject to FDA Authority

■ 3. Revise § 1100.1 to read as follows:

§ 1100.1 Scope.

In addition to FDA's authority over cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and any tobacco product containing nicotine not made or derived from tobacco, FDA deems all other products meeting the definition of *tobacco product* under section 201(rr) of the Federal Food, Drug, and Cosmetic Act, except accessories of such other tobacco products, to be subject to the Federal Food, Drug, and Cosmetic Act.

§ 1100.2 [Amended]

■ 4. In § 1100.2, in the first sentence, add the words '', and any tobacco product containing nicotine not made or derived from tobacco'' after ''smokeless tobacco''.

■ 5. In § 1100.3, revise the definition of ''Tobacco product'' to read as follows:

§ 1100.3 Definitions.

* * * * *

Tobacco product, as stated in section 201(rr) of the Federal Food, Drug, and Cosmetic Act in relevant part:

(1) Means any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product); and

(2) Does not mean an article that is a drug under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act; a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act; a combination product described in section 503(g) of the Federal Food, Drug, and Cosmetic Act; or a food under 201(f) of the Federal Food, Drug, and Cosmetic Act if such article contains no nicotine or no more than trace amounts of naturally occurring nicotine.

■ 6. In § 1100.202, revise the definition of ''Tobacco product'' to read as follows:

§ 1100.202 Definitions.

* * * * *

Tobacco product means any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). The term ''tobacco product'' does not mean an article that under the Federal Food, Drug, and Cosmetic Act is: a drug (section 201(g)(1)); a device (section 201(h)); a combination product (section 503(g)); or a food (section 201(f)) if such article contains no nicotine or no more than trace amounts of naturally occurring nicotine.

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PART 1107—EXEMPTION REQUESTS AND SUBSTANTIAL EQUIVALENCE REPORTS

■ 7. The authority citation for part 1107 is revised to read as follows:

Authority: 21 U.S.C. 371, 374, 387e(j), 387i, 387j; Pub. L. 117–103, 136 Stat. 49.

■ 8. In § 1107.12, revise the definition of ''Tobacco product'' to read as follows:

§ 1107.12 Definitions.

* * * * *

Tobacco product means any product made or derived from tobacco, or containing nicotine from any source, that is intended for human

[2] See Section III for additional information about the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521) as it relates to the regulations listed in table 1.

consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). The term ''tobacco product'' does not mean an article that under the Federal Food, Drug, and Cosmetic Act is: a drug (section 201(g)(1)); a device (section 201(h)); a combination product (section 503(g)); or a food (section 201(f)) if such article contains no nicotine or no more than trace amounts of naturally occurring nicotine.

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PART 1114—PREMARKET TOBACCO PRODUCT APPLICATIONS

■ 9. The authority citation for part 1114 is revised to read as follows:

Authority: 21 U.S.C. 371, 374, 387a, 387i, 387j; Pub. L. 117–103, 136 Stat. 49.

■ 10. In § 1114.3, revise the definition of ''Tobacco product'' to read as follows:

§ 1114.3 Definitions.

* * * * *

Tobacco product means any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). The term ''tobacco product'' does not mean an article that under the Federal Food, Drug, and Cosmetic Act is: a drug (section 201(g)(1)); a device (section 201(h)); a combination product (section 503(g)); or a food (section 201(f)) if such article contains no nicotine or no more than trace amounts of naturally occurring nicotine.

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PART 1140—CIGARETTES, SMOKELESS TOBACCO, AND COVERED TOBACCO PRODUCTS

■ 11. The authority citation for part 1140 is revised to read as follows:

Authority: 21 U.S.C. 301 *et seq.,* 21 U.S.C. 387a–1, and Pub. L. 117–103, 136 Stat. 49.

■ 12. In § 1140.3, revise the definition of ''Tobacco product'' to read as follows:

§ 1140.3 Definitions.

* * * * *

Tobacco product, as stated in section 201(rr) of the Federal Food, Drug, and Cosmetic Act in relevant part:

(1) Means any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product); and

(2) Does not mean an article that is a drug under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act; a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act; a combination product described in section 503(g) of the Federal Food, Drug, and Cosmetic Act; or a food under 201(f) of the Federal Food, Drug, and Cosmetic Act if such article contains no nicotine or no more than trace amounts of naturally occurring nicotine.

PART 1143—MINIMUM REQUIRED WARNING STATEMENTS

■ 13. The authority citation for part 1143 is revised to read as follows:

Authority: 21 U.S.C. 387a(b), 387f(d), Pub. L. 117–103, 136 Stat. 49.

■ 14. In § 1143.1, revise the definition of ''Tobacco product'' to read as follows:

§ 1143.1 Definitions.

* * * * *

Tobacco product, as stated in section 201(rr) of the Federal Food, Drug, and Cosmetic Act in relevant part:

(1) Means any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product); and

(2) Does not mean an article that is a drug under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act; a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act; a combination product described in section 503(g) of the Federal Food, Drug, and Cosmetic Act; or a food under 201(f) of the Federal Food, Drug, and Cosmetic Act if such article contains no nicotine or no more than trace amounts of naturally occurring nicotine.

Dated: February 22, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2023–0220]

RIN 1625–AA00

Safety Zone; Atlantic Ocean, Cape Canaveral Offshore Launch Area, FL

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for waters of the Atlantic Ocean, adjacent to Cape Canaveral, FL. This safety zone would implement a special activities provision of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021. The Coast Guard is establishing this safety zone for the launch of the Terran 1 rocket, which is being launched by Relativity Space. The temporary safety zone will be located within the Coast Guard District Seven area of responsibility offshore of Cape Canaveral, Florida. This rule prohibits U.S.-flagged vessels from entering the temporary safety zone unless authorized by the District Commander of the Seventh Coast Guard District or a designated representative. Foreign-flagged vessels are encouraged to remain outside the safety zone. This action is necessary to protect vessels and waterway users from the potential hazards created by launch of the Terran 1 rocket, flying over the U.S. Exclusive Economic Zone (EEZ).

DATES: This rule is effective without actual notice from March 20, 2023, through 4 p.m. on March 23, 2023. For the purposes of enforcement, actual notice will be used from 10 a.m. on March 16, 2023, through March 20, 2023.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2022–0220 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email LT Ryan Gilbert, District Seven, Waterways Management Branch, U.S. Coast Guard; telephone 305–415–6750, email *Ryan.A.Gilbert@uscg.mil.*

SUPPLEMENTARY INFORMATION: