and confidential commercial information, or in § 20.63 of this chapter for personal privacy

(d) *Disclosure of data and information after the issuance of a marketing denial order*. After FDA issues a marketing denial order, FDA may make certain information related to the application and the order available for public disclosure upon request or at FDA's own initiative unless the information is otherwise exempt from disclosure under part 20 of this chapter. Information FDA may disclose includes, but is not limited to the tobacco product category (*e.g.*, cigarette), tobacco product subcategory (*e.g.*, filtered, combusted cigarette), package size, product quantity, characterizing flavor, and the basis for the marketing denial order.

§ 1114.49 Electronic submission.

(a) *Electronic format requirement*. Applicants submitting any documents to the Agency under this part must provide all required information to FDA using the Agency's electronic system, except as provided in paragraph (b) of this section. The application and all supporting information must be submitted in an electronic format that FDA can process, review, and archive.

(b) *Waivers from electronic format requirement*. An applicant may submit a written request, that is legible and in English, to the Center for Tobacco Products asking that FDA waive the requirement for electronic format and content. Waivers will be granted if use of electronic means is not reasonable for the applicant. To request a waiver, applicants can send the written request to the address included on our website (*www.fda.gov/tobacco-products*). The request must include the following information:

(1) The name and address of the applicant, a list of individuals authorized by the applicant to serve as the contact person and contact information. If the applicant has submitted a PMTA previously, the regulatory correspondence should also include any identifying information about the previous submission.

(2) A statement that creation and/or submission of information in electronic format is not reasonable for the applicant, and an explanation of why creation and/or submission in electronic format is not reasonable. This statement must be signed by the applicant or by a representative who is authorized to make the declaration on behalf of the applicant.

(c) *Paper submission*. An applicant who has obtained a waiver from filing electronically must send a written application through the Document Control Center to the address provided in the FDA documentation granting the waiver.

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

Subpart A—General Provisions

Sec.
1140.1 Scope.
1140.2 Purpose.
1140.3 Definitions.

Subpart B—Prohibition of Sale and Distribution to Persons Younger Than 18 Years of Age

1140.10 General responsibilities of manufacturers, distributors, and retailers.
1140.12 Additional responsibilities of manufacturers.
1140.14 Additional responsibilities of retailers.
1140.16 Conditions of manufacture, sale, and distribution.

Subpart C [Reserved]

Subpart D—Labeling and Advertising

1140.30 Scope of permissible forms of labeling and advertising.
1140.32 Format and content requirements for labeling and advertising.
1140.34 Sale and distribution of nontobacco items and services, gifts, and sponsorship of events.

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

SOURCE: 75 FR 13230, Mar. 19, 2010, unless otherwise noted.

Subpart A—General Provisions

§ 1140.1 Scope.

(a) This part sets out the restrictions under the Federal Food, Drug, and Cosmetic Act on the sale, distribution, and use of cigarettes, smokeless tobacco, and covered tobacco products. Section

1140.16(d) sets out restrictions on the distribution of free samples for cigarettes, smokeless tobacco, and other tobacco products (as such term is defined in section 201 of the Federal Food, Drug, and Cosmetic Act).

(b) The failure to comply with any applicable provision in this part in the sale, distribution, and use of cigarettes, smokeless tobacco, covered tobacco products, or other tobacco products renders the product misbranded under the Federal Food, Drug, and Cosmetic Act.

(c) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

[81 FR 29102, May 10, 2016]

§ 1140.2 Purpose.

The purpose of this part is to establish restrictions on the sale, distribution, and use of cigarettes, smokeless tobacco, and covered tobacco products in order to reduce the number of children and adolescents who use these products, and to reduce the life-threatening consequences associated with tobacco use.

[81 FR 29102, May 10, 2016]

§ 1140.3 Definitions.

For the purposes of this part:

Accessory means any product that is intended or reasonably expected to be used with or for the human consumption of a tobacco product; does not contain tobacco and is not made or derived from tobacco; and meets either of the following:

(1) Is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product; or

(2) Is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product but

(i) Solely controls moisture and/or temperature of a stored product; or

(ii) Solely provides an external heat source to initiate but not maintain combustion of a tobacco product.

Cigarette. (1) Means a product that:

(i) Is a tobacco product and

(ii) Meets the definition of the term ''cigarette'' in section 3(1) of the Federal Cigarette Labeling and Advertising Act; and

(2) Includes tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own tobacco.

Cigarette tobacco means any product that consists of loose tobacco that is intended for use by consumers in a cigarette. Unless otherwise stated, the requirements applicable to cigarettes under this chapter also apply to cigarette tobacco.

Component or *part* means any software or assembly of materials intended or reasonably expected:

(1) To alter or affect the tobacco product's performance, composition, constituents, or characteristics; or

(2) To be used with or for the human consumption of a tobacco product. Component or part excludes anything that is an accessory of a tobacco product.

Covered tobacco product means any tobacco product deemed to be subject to the Federal Food, Drug, and Cosmetic Act under §1100.2 of this chapter, but excludes any component or part that is not made or derived from tobacco.

Distributor means any person who furthers the distribution of a tobacco product, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption. Common carriers are not considered distributors for the purposes of this part.

Importer means any person who imports any tobacco product that is intended for sale or distribution to consumers in the United States.

Manufacturer means any person, including any repacker and/or relabeler, who manufactures, fabricates, assembles, processes, or labels a finished tobacco product.

Nicotine means the chemical substance named 3-(1-Methyl-2-pyrrolidinyl)pyridine or C[10]H[14]N[2], including any salt or complex of nicotine.

Package or *packaging* means a pack, box, carton, or container of any kind

or, if no other container, any wrapping (including cellophane) in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers.

Point of sale means any location at which a consumer can purchase or otherwise obtain tobacco products for personal consumption.

Retailer means any person who sells tobacco products to individuals for personal consumption, or who operates a facility where vending machines or self-service displays are permitted under this part.

Roll-your-own tobacco means any tobacco product that, because of its appearance, type, packaging, or labeling, is suitable for use and likely to be offered to, or purchased by, consumers as tobacco for making cigarettes.

Smokeless tobacco means any tobacco product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity.

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.

[81 FR 29102, May 10, 2016, as amended at 88 FR 16553, Mar. 20, 2023]

Subpart B—Prohibition of Sale and Distribution to Persons Younger Than 18 Years of Age

§ 1140.10 General responsibilities of manufacturers, distributors, and retailers.

Each manufacturer, distributor, importer, and retailer is responsible for ensuring that the cigarettes, smokeless tobacco, or covered tobacco products it manufactures, labels, advertises, packages, distributes, imports, sells, or otherwise holds for sale comply with all applicable requirements under this part.

[81 FR 29103, May 10, 2016]

§ 1140.12 Additional responsibilities of manufacturers.

In addition to the other responsibilities under this part, each manufacturer shall remove from each point of sale all self-service displays, advertising, labeling, and other items that the manufacturer owns that do not comply with the requirements under this part.

§ 1140.14 Additional responsibilities of retailers.

(a) In addition to the other requirements under this part, each cigarette and smokeless tobacco retailer is responsible for ensuring that all sales of cigarettes or smokeless tobacco to any person comply with the following requirements:

(1) No retailer may sell cigarettes or smokeless tobacco to any person younger than 18 years of age;

(2)(i) Except as otherwise provided in paragraph (a)(2)(ii) of this section and in §1140.16(c)(2)(i), each retailer must verify by means of photographic identification containing the bearer's date of birth that no person purchasing the product is younger than 18 years of age;

(ii) No such verification is required for any person over the age of 26;

(3) Except as otherwise provided in §1140.16(c)(2)(ii), a retailer may sell cigarettes or smokeless tobacco only in a direct, face-to-face exchange without the assistance of any electronic or mechanical device (such as a vending machine);

(4) No retailer may break or otherwise open any cigarette or smokeless tobacco package to sell or distribute individual cigarettes or a number of unpackaged cigarettes that is smaller than the quantity in the minimum cigarette package size defined in §1140.16(b), or any quantity of cigarette tobacco or smokeless tobacco that is smaller than the smallest package distributed by the manufacturer for individual consumer use; and

(5) Each retailer must ensure that all self-service displays, advertising, labeling, and other items, that are located in the retailer's establishment and that do not comply with the requirements of this part, are removed or are brought into compliance with the requirements under this part.

(b) Notwithstanding the requirements in paragraph (a) of this section and in addition to the other requirements under this part, each retailer of covered tobacco products is responsible for ensuring that all sales of such covered tobacco products to any person comply with the following requirements:

(1) No retailer may sell covered tobacco products to any person younger than 18 years of age;

(2)(i) Except as otherwise provided in paragraph (a)(2)(ii) of this section and in §1140.16(c)(2)(i), each retailer must verify by means of photographic identification containing the bearer's date of birth that no person purchasing the product is younger than 18 years of age;

(ii) No such verification is required for any person over the age of 26; and

(3) A retailer may not sell covered tobacco products with the assistance of any electronic or mechanical device (such as a vending machine), except in facilities where the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time.

[81 FR 29103, May 10, 2016]

§ 1140.16 Conditions of manufacture, sale, and distribution.

(a) *Restriction on product names.* A manufacturer shall not use a trade or brand name of a nontobacco product as the trade or brand name for a cigarette or smokeless tobacco product, except for a tobacco product whose trade or brand name was on both a tobacco product and a nontobacco product that were sold in the United States on January 1, 1995.

(b) *Minimum cigarette package size.* Except as otherwise provided under this section, no manufacturer, distributor, or retailer may sell or cause to be sold, or distribute or cause to be distributed, any cigarette package that contains fewer than 20 cigarettes.

(c) *Vending machines, self-service displays, mail-order sales, and other ''impersonal'' modes of sale.* (1) Except as otherwise provided under this section, a retailer may sell cigarettes and smokeless tobacco only in a direct, face-to-face exchange between the retailer and the consumer. Examples of methods of sale that are not permitted include vending machines and self-service displays.

(2) *Exceptions.* The following methods of sale are permitted:

(i) Mail-order sales, excluding mail-order redemption of coupons and distribution of free samples through the mail; and

(ii) Vending machines (including vending machines that sell packaged, single cigarettes) and self-service displays that are located in facilities where the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time.

(d)(1) Except as provided in paragraph (d)(2) of this section, no manufacturer, distributor, or retailer may distribute or cause to be distributed any free samples of cigarettes, smokeless tobacco, or other tobacco products (as such term is defined in section 201 of the Federal Food, Drug, and Cosmetic Act).

(2)(i) Paragraph (d)(1) of this section does not prohibit a manufacturer, distributor, or retailer from distributing or causing to be distributed free samples of smokeless tobacco in a qualified adult-only facility.

(ii) Paragraph (d)(2) of this section does not affect the authority of a State or local government to prohibit or otherwise restrict the distribution of free samples of smokeless tobacco.

(iii) For purposes of paragraph (d) of this section, the term ''qualified adult-

only facility'' means a facility or restricted area that:

(A) Requires each person present to provide to a law enforcement officer (whether on or off duty) or to a security guard licensed by a governmental entity government-issued identification showing a photograph and at least the minimum age established by applicable law for the purchase of smokeless tobacco;

(B) Does not sell, serve, or distribute alcohol;

(C) Is not located adjacent to or immediately across from (in any direction) a space that is used primarily for youth-oriented marketing, promotional, or other activities;

(D) Is a temporary structure constructed, designated, and operated as a distinct enclosed area for the purpose of distributing free samples of smokeless tobacco in accordance with this paragraph (d)(2) of this section;

(E) Is enclosed by a barrier that:

(*1*) Is constructed of, or covered with, an opaque material (except for entrances and exits);

(*2*) Extends from no more than 12 inches above the ground or floor (which area at the bottom of the barrier must be covered with material that restricts visibility but may allow airflow) to at least 8 feet above the ground or floor (or to the ceiling); and

(*3*) Prevents persons outside the qualified adult-only facility from seeing into the qualified adult-only facility, unless they make unreasonable efforts to do so; and

(F) Does not display on its exterior:

(*1*) Any tobacco product advertising;

(*2*) A brand name other than in conjunction with words for an area or enclosure to identify an adult-only facility; or

(*3*) Any combination of words that would imply to a reasonable observer that the manufacturer, distributor, or retailer has a sponsorship that would violate § 1140.34(c).

(iv) Distribution of samples of smokeless tobacco under paragraph (d)(2) of this section permitted to be taken out of the qualified adult-only facility shall be limited to one package per adult consumer containing no more than 0.53 ounces (15 grams) of smokeless tobacco. If such package of smokeless tobacco contains individual portions of smokeless tobacco, the individual portions of smokeless tobacco shall not exceed eight individual portions, and the collective weight of such individual portions shall not exceed 0.53 ounces (15 grams). Any manufacturer, distributor, or retailer who distributes or causes to be distributed free samples also shall take reasonable steps to ensure that the amounts in this paragraph (d)(2)(iv) are limited to one such package per adult consumer per day.

(3) Notwithstanding paragraph (d)(2) of this section, no manufacturer, distributor, or retailer may distribute or cause to be distributed any free samples of smokeless tobacco:

(i) To a sports team or entertainment group; or

(ii) At any football, basketball, baseball, soccer, or hockey event or any other sporting or entertainment event determined by the Secretary to be covered by paragraph (d)(3) of this section.

(4) The Secretary shall implement a program to ensure compliance with paragraph (d) of this section and submit a report to the Congress on such compliance not later than 18 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act.

(5) Nothing in paragraph (d) of this section shall be construed to authorize any person to distribute or cause to be distributed any sample of a tobacco product to any individual who has not attained the minimum age established by applicable law for the purchase of such product.

(e) *Restrictions on labels, labeling, and advertising.* No manufacturer, distributor, or retailer may sell or distribute, or cause to be sold or distributed, cigarettes or smokeless tobacco with labels, labeling, or advertising not in compliance with subpart D of this part, and other applicable requirements.

Subpart C [Reserved]

Subpart D—Labeling and Advertising

§ 1140.30 Scope of permissible forms of labeling and advertising.

(a)(1) A manufacturer, distributor, or retailer may, in accordance with this subpart D, disseminate or cause to be disseminated advertising or labeling which bears a cigarette or smokeless tobacco brand name (alone or in conjunction with any other word) or any other indicia of tobacco product identification, in newspapers; in magazines; in periodicals or other publications (whether periodic or limited distribution); on billboards, posters, and placards; in nonpoint-of-sale promotional material (including direct mail); in point-of-sale promotional material; and in audio or video formats delivered at a point-of-sale.

(2) A manufacturer, distributor, or retailer intending to disseminate, or to cause to be disseminated, advertising or labeling for cigarettes or smokeless tobacco in a medium that is not listed in paragraph (a)(1) of this section, shall notify the agency 30 days prior to the use of such medium. The notice shall describe the medium and discuss the extent to which the advertising or labeling may be seen by persons younger than 18 years of age. The manufacturer, distributor, or retailer shall send this notice to the Office of Compliance and Enforcement, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993.

(b) [Reserved]

(c) This subpart D does not apply to cigarette or smokeless tobacco package labels.

[75 FR 13230, Mar. 19, 2010, as amended at 83 FR 13183, Mar. 28, 2018]

§ 1140.32 Format and content requirements for labeling and advertising.

(a) Except as provided in paragraph (b) of this section, each manufacturer, distributor, and retailer advertising or causing to be advertised, disseminating or causing to be disseminated, any labeling or advertising for cigarettes or smokeless tobacco shall use only black text on a white background. This section does not apply to advertising:

(1) In any facility where vending machines and self- service displays are permitted under this part, provided that the advertising is not visible from outside the facility and that it is affixed to a wall or fixture in the facility; or

(2) Appearing in any publication (whether periodic or limited distribution) that the manufacturer, distributor, or retailer demonstrates is an adult publication. For the purposes of this section, an adult publication is a newspaper, magazine, periodical, or other publication:

(i) Whose readers younger than 18 years of age constitute 15 percent or less of the total readership as measured by competent and reliable survey evidence; and

(ii) That is read by fewer than 2 million persons younger than 18 years of age as measured by competent and reliable survey evidence.

(b) Labeling and advertising in an audio or video format shall be limited as follows:

(1) Audio format shall be limited to words only with no music or sound effects.

(2) Video formats shall be limited to static black text only on a white background. Any audio with the video shall be limited to words only with no music or sound effects.

§ 1140.34 Sale and distribution of nontobacco items and services, gifts, and sponsorship of events.

(a) No manufacturer and no distributor of imported cigarettes or smokeless tobacco may market, license, distribute, sell, or cause to be marketed, licensed, distributed, or sold any item (other than cigarettes or smokeless tobacco or roll-your-own paper) or service, which bears the brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco.

(b) No manufacturer, distributor, or retailer may offer or cause to be offered any gift or item (other than cigarettes or smokeless tobacco) to any

person purchasing cigarettes or smokeless tobacco in consideration of the purchase thereof, or to any person in consideration of furnishing evidence, such as credits, proofs-of-purchase, or coupons, of such a purchase.

(c) No manufacturer, distributor, or retailer may sponsor or cause to be sponsored any athletic, musical, artistic, or other social or cultural event, or any entry or team in any event, in the brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco. Nothing in this paragraph prevents a manufacturer, distributor, or retailer from sponsoring or causing to be sponsored any athletic, musical, artistic, or other social or cultural event, or team or entry, in the name of the corporation which manufactures the tobacco product, provided that both the corporate name and the corporation were registered and in use in the United States prior to January 1, 1995, and that the corporate name does not include any brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco.

PART 1141—CIGARETTE PACKAGE AND ADVERTISING WARNINGS (eff. until 11-6-23)

Subpart A—General Provisions

Subpart B—Cigarette Package and Advertising Warnings

Subpart C—Additional Disclosure Requirements for Cigarette Packages and Advertising

AUTHORITY: 15 U.S.C. 1333; 21 U.S.C. 371, 387c, 387f; Secs. 201 and 202, Pub. L. 111–31, 123 Stat. 1776.

SOURCE: 76 FR 36753, June 22, 2011, unless otherwise noted.

EFFECTIVE DATE NOTE: At 85 FR 15708, Mar. 8, 2020, part 1141 was revised, effective June. 18, 2021. At 85 FR 32296, May 29, 2020, the effective date was delayed to delayed until Oct. 16, 2021. At 86 FR 3793, Jan. 14, 2021, this amended was further delayed until Jan. 14, 2022. At 86 FR 36509, July 12, 2021, this amendment was further delayed until July 13, 2022. At 86 FR 50855, Sept. 13, 2021, this amendment was further delayed until Oct. 11, 2022. At 86 FR 70052, Dec. 9, 2021, this amendment was further delayed until Jan. 9, 2023. At 87 FR 11295, Mar. 1, 2022, this amendment further delayed until Apr. 9, 2023. At 87 FR 32990, June 1, 2022, this amendment further delayed until July 8, 2023. At 87 FR 50765, Aug. 18, 2022, this amendment further delayed until Oct. 9, 2023. At 87 FR 72387, Nov. 25, 2022, this amendment further delayed until Nov. 6, 2023. For the convenience of the user, the new part 1141 follows the text of this part.

Subpart A—General Provisions

§ 1141.1 Scope.

(a) This part sets forth the requirements for the display of health warnings on cigarette packages and in advertisements for cigarettes. FDA may require additional statements to be displayed on packages and in advertisements under the Federal Food, Drug, and Cosmetic Act or other authorities.

(b) The requirements of this part do not apply to manufacturers or distributors of cigarettes that do not manufacture, package, or import cigarettes for sale or distribution within the United States.

(c) A cigarette retailer shall not be considered in violation of this part as it applies to the display of health warnings on a cigarette package if the package:

(1) Contains a health warning;

(2) Is supplied to the retailer by a license- or permit-holding tobacco