Compliance Policy for Required Warning Statements on Small-Packaged Cigars (Revised)*

Guidance for Industry

Comments may be submitted at any time for Agency consideration. Electronic comments may be submitted to http://www.regulations.gov. Alternatively, submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD, 20852. All comments should be identified with FDA-2017-D-0121.

For questions regarding this guidance, contact the Center for Tobacco Products at (Tel) 1-877-CTP-1373 (1-877-287-1373) Monday-Friday, 9 a.m. – 4 p.m. EDT.

Additional copies are available online at http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm. You may send an e-mail request to SmallBiz.Tobacco@fda.hhs.gov to receive an electronic copy of this guidance. You may send a request for hard copies to U.S. Food and Drug Administration, Center for Tobacco Products, Attn: Office of Small Business Assistance, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-2000.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Tobacco Products

August 2018

*This is the first revision to this guidance. The first edition was published in September 2017.

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Contains Nonbinding Recommendations

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Guidance for Industry[1]

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. 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. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance document is intended to assist any person who manufactures, packages, sells, offers to sell, distributes, or imports cigars in small packages with respect to the warning statement requirements in Title 21, Code of Federal Regulations (CFR), part 1143 (21 CFR part 1143) for product packaging. This guidance document discusses, among other things:

- The regulatory requirements to place specific warnings on cigar packaging
- Definitions
- FDA's compliance policy for cigars in small packaging

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

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[1] This guidance was prepared by the Office of Regulations and the Office of Compliance and Enforcement in the Center for Tobacco Products at FDA.

II. BACKGROUND

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111-31) was signed into law. The Tobacco Control Act granted FDA the authority to regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, roll-your-own (RYO) tobacco, and smokeless tobacco products to protect the public health and to reduce tobacco use by minors.

The Tobacco Control Act also gave FDA the authority to issue a regulation deeming other products that meet the statutory definition of a tobacco product to be subject to chapter IX of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (deeming) (section 901(b) of the FD&C Act (21 U.S.C. 387a(b))). On May 10, 2016, FDA issued the deeming rule, extending FDA's tobacco product authority to cigars, among other products (81 FR 28973). Among the requirements that now apply to newly deemed products such as cigars are health warning statements prescribed under section 906(d) of the FD&C Act (21 U.S.C. 387f(d)), which permits restrictions on the sale and distribution of tobacco products that are "appropriate for the protection of the public health."

On July 5, 2018, the U.S. District Court for the District of Columbia enjoined FDA from enforcing the warning requirements for cigars and pipe tobacco (21 CFR §§ 1143.3 and 1143.5) until 60 days after the final disposition of the plaintiffs' appeal in the case: *Cigar Ass'n of America v. FDA*, No. 1:16-cv-01460 (D.D.C.) (order granting injunction pending appeal); *see also Cigar Ass'n of America v. FDA*, No. 18-5195 (D.C. Cir.). FDA will not seek to enforce the warning requirements for cigars and pipe tobacco until that order is lifted. Once the warning statement requirements take effect,[2] it will be unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any cigar unless the product package bears one of the following required warning statements listed in §1143.5(a)[3]:

- WARNING: This product contains nicotine. Nicotine is an addictive chemical.
- WARNING: Cigar smoking can cause cancers of the mouth and throat, even if you do not inhale.
- WARNING: Cigar smoking can cause lung cancer and heart disease.
- WARNING: Cigars are not a safe alternative to cigarettes.

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[2] The effective date under the deeming rule is May 10, 2018. FDA issued a guidance on May 10, 2017 providing a compliance date of August 10, 2018. See https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM557716.pdf. As stated above, FDA will not enforce the warning requirements for cigars and pipe tobacco at this time.

[3] Retailers may continue to sell and distribute tobacco products with packaging that does not bear the required health warning statements after the effective date, but only if the products were manufactured before the effective date of the warning statement requirements. *See* 21 CFR1143.13(a). For more information on compliance dates, see FDA's guidance for industry, Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule (August, 2018), available at: https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm557714.htm.

- WARNING: Tobacco smoke increases the risk of lung cancer and heart disease, even in nonsmokers.
- WARNING: Cigar use while pregnant can harm you and your baby.
  Or
  SURGEON GENERAL WARNING: Tobacco Use Increases the Risk of Infertility, Stillbirth and Low Birth Weight.[4]

These required warning statements for packages must be randomly displayed and distributed in accordance with a warning plan submitted to and approved by FDA (see the guidance, *Submission of Warning Plans for Cigars (August 2018)*.[5] Warning plans should be submitted to FDA no later than either 12 months after May 10, 2016, or 12 months before advertising or commercially marketing a product that is subject to such requirement, whichever is later (§ 1143.5(c)(3)). On May 10, 2017, FDA issued a guidance, which, among other things, provided a compliance date of August 10, 2017 for the warning plan requirement. Therefore, warning plans for tobacco products on the market as of August 8, 2016 that are subject to these requirements were expected to be submitted to FDA by August 10, 2017.

Section 1143.5(a)(2) specifies that the required warning statements for cigars must comprise at least 30 percent of each of the two principal display panels of the cigar package and must appear in at least 12-point font, among other display and formatting requirements.

Section 1143.3 specifies the warning statement requirements for cigarette tobacco, RYO tobacco, and covered tobacco products other than cigars. Section 1143.3(d) provides a small package exemption from the required warning statement for these tobacco products, but excludes cigars. According to this section, if a tobacco product package is too small or otherwise unable to accommodate a label with sufficient space to bear such information, it will be exempt from the requirement to place the required warning statement directly on the product package provided that the required warning statement appears:

- On the carton or other outer container or wrapper if the carton, outer container, or wrapper has sufficient space to bear the information; or
- On a tag otherwise firmly and permanently affixed to the tobacco product package.

Under this provision, the required warning statement must be printed using the specifications required in § 1143.3(a)(2), including warning placement, size, and font. In these cases, the carton, outer container, wrapper, or tag would serve as the location for the principal display panels. If a tag is used for the principal display panels, both sides of the

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[4] You may choose to display either one of the warning statements regarding reproductive health. FDA is allowing the use of the reproductive health warning statement as required by the Federal Trade Commission (FTC) consent decrees as an optional alternative to the FDA warning, "WARNING: Cigar use while pregnant can harm you and your baby." FDA expects that providing this optional alternative will benefit entities bound by the FTC consent decrees, and the statement is appropriate for the protection of public health.

[5] See https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm517680.htm

tag must be visible to the consumer (81 FR 29060). The required warning statements must be printed on both sides of the tag to comply with § 1143.3(a)(2).

Part 1143 has no similar exemption for cigars with packaging that is too small or otherwise unable to accommodate a label with sufficient space to bear the required warning statements. Cigars that are sold individually, without any packaging, may satisfy the warning requirements for packages with warning statements posted at the point of sale as specified in § 1143.5(a)(3). This guidance addresses cigars with packaging that is too small or otherwise unable to accommodate a label with sufficient space to bear the required warning statements.

III. DISCUSSION

A. What Definitions Apply to This Guidance?

For purposes of this guidance, FDA intends to use the following definitions, some of which are included in § 1143.1:

Cigar means a tobacco product that: (1) is not a cigarette; and (2) is a roll of tobacco wrapped in leaf tobacco or any substance containing tobacco.

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.

Principal display panels means the panels of a package that are most likely to be displayed, presented, shown, or examined by the consumer.

Required warning statement means a textual warning statement required to be on packaging and in advertisements for cigarette tobacco, RYO tobacco, cigars, and other covered tobacco products, pursuant to § 1143.3 and § 1143.5.

B. FDA's Compliance Policy for Cigars in Small Packaging

This guidance sets forth FDA's compliance policy with respect to cigars in packaging that is too small or otherwise unable to accommodate a label with sufficient space to bear the required warning statements. At this time, FDA does not intend to take enforcement action with respect to such cigars that do not comply with the size and placement requirements in § 1143.5(a)(2) when the information and specifications required under § 1143.5(a)(1) and (a)(2) appear on the carton or other outer container or wrapper that could accommodate the required warning statements, or on a tag otherwise firmly and permanently affixed to the cigar package.[6] This guidance does not apply to the other provisions of § 1143.5, including

[6] This is similar to the approach provided in § 1143.3(d) for cigarette tobacco, RYO tobacco, and covered tobacco products other than cigars.

the random display and distribution of cigar warning statements on packaging in accordance with an FDA-approved warning plan, as described in § 1143.5(c).

IV. DOCUMENT HISTORY

September 2017 — First edition of guidance issued.

August 2018 — Section II is revised to reflect a stay of enforcement of the warning requirements for cigars and pipe tobacco (21 CFR §§ 1143.3 and 1143.5) after the United States District Court for the District of Columbia granted plaintiffs' motion for an injunction pending appeal. *Cigar Ass'n of America v. FDA*, No. 1:16-cv-01460 (D.D.C.) (order granting injunction pending appeal).

— Clarifying and corrective edits made throughout the guidance.