

Compliance Policy for Certain Labeling and Warning Statement Requirements for Cigars and Pipe Tobacco

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-2018-D-3047.

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**

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*This is the first edition of this guidance.

Table of Contents

I. INTRODUCTION..... 1

II. BACKGROUND 2

III. DISCUSSION..... 3

A. What Definitions Apply to This Guidance?..... 3

B. FDA’s Compliance Policy for Certain Labeling and Warning Statement Requirements for Cigars and Pipe Tobacco.....3

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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 or pipe tobacco with respect to the labeling requirements in sections 903(a)(2) and 920(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 387c(a)(2), 387t(a)) and the warning statement requirements in Title 21, Code of Federal Regulations (CFR), part 1143 (21 CFR part 1143). This guidance document discusses, among other things:

- Certain statutory requirements for pipe tobacco and cigar labeling
- The regulatory requirements for cigar and pipe tobacco warning statements
- Definitions
- FDA's compliance policy for certain labeling and warning statement requirements for cigars and pipe tobacco

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

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.

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requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

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 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 final deeming rule, extending FDA's tobacco product authority to all other products (other than accessories of newly deemed products) that meet the statutory definition of tobacco product, including cigars and pipe tobacco (81 FR 28973).

When the regulation became effective in August 2016, deemed products immediately became subject to Chapter IX of the FD&C Act and its implementing regulations, including the misbranding provision at section 903 of the FD&C Act (21 U.S.C. 387c). The misbranding provision includes a requirement under section 903(a)(2) of the FD&C Act (21 U.S.C. 387c(a)(2)) that a tobacco product in package form must bear a label that contains information about the name and place of business of the tobacco product manufacturer, packer, or distributor; an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; an accurate statement of the percentage of domestic and foreign-grown tobacco used in the product; and the statement required by section 920(a) of the FD&C Act (21 U.S.C. 387t(a)) (i.e., "sale only allowed in the United States").

In addition, the regulation at 21 C.F.R. part 1143 requires that cigarette tobacco, roll-your-own tobacco, and covered tobacco products include warning statements on product package labels and advertisements. When FDA issued the final deeming rule, it recognized that making these required label changes at one time could decrease the cost of compliance on industry; accordingly, as provided for in the preamble to the final deeming rule, the compliance date for the labeling requirements under sections 903(a)(2) and 920(a) of the FD&C Act matched the effective date for the warnings requirements.²

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

² See 81 FR at 29,006.

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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.).

III. DISCUSSION

A. What Definitions Apply to This Guidance?

For purposes of this guidance, FDA intends to use the following definitions:

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.

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 Certain Labeling and Warning Statement Requirements for Cigars and Pipe Tobacco

FDA intends to comply with the court's order in *Cigar Association of America* and will not enforce the warning statement requirements for cigars and pipe tobacco until 60 days after the final disposition of Plaintiffs' appeal. In addition, the agency does not intend to enforce the labeling requirements under sections 903(a)(2) and 920(a) for cigars and pipe tobacco while the injunction remains in effect.³ Cigar and pipe tobacco firms, however, may add the warnings and make these labeling changes while the injunction remains in effect. The compliance policy in this guidance supersedes the compliance dates included in any other guidance issued prior to this guidance.

The court's order does not enjoin FDA from enforcing the warning requirements at 21 C.F.R. § 1143.3 for other covered tobacco products, cigarette tobacco, and roll-your-own

³ This is consistent with the approach the agency took after the district court decision in *R.J. Reynolds Tobacco Co. v. U.S. Food and Drug Administration*, 823 F. Supp. 2d 36 (D.D.C. 2011), while the case was on appeal, Nos. 11-553, 12-5063 (D.C. Cir.). Due to ongoing litigation, the implementation of FDA's final rule entitled "Required Warnings for Cigarette Packages and Advertisements" was uncertain. Although the requirement under section 903(a)(2) of the FD&C Act was not the subject of that litigation, given the uncertainties caused by the ongoing litigation, the agency explained that those who manufacture, package, sell, offer to sell, distribute or import for sale or distribution cigarettes within the United States would not be expected to comply with section 903(a)(2) until further notice from FDA.

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tobacco. Accordingly, these categories of products would not be subject to the compliance policy described above.⁴

⁴ FDA issued a Draft Guidance titled “Interpretation of and Compliance Policy for Certain Label Requirement; Applicability of Certain Food, Drug, and Cosmetic Act Requirements to Vape Shops” for public comment, which, among other things, included a compliance policy relating to section 903(a)(2)(C). When finalized, the guidance will reflect the agency’s current thinking on the topics contained therein.