Interpretation of and Compliance Policy for Certain Label Requirement; Applicability of Certain Federal Food, Drug, and Cosmetic Act Requirements to Vape Shops

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Guidance for Industry

GUIDANCE

Comments may be submitted at any time for Agency consideration. Electronic comments may be submitted to https://www.regulations.gov. Alternatively, submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. All comments should be identified with Docket No. FDA-2017-D-0120.

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 https://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
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Interpretation of and Compliance Policy for Certain Label Requirement; Applicability of Certain Federal Food, Drug, and Cosmetic Act Requirements to Vape Shops

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 retailers[2] who sell newly deemed products[3] by explaining whether engaging in certain activities subjects such establishments to additional requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and identifying the limited circumstances under which FDA does not intend to enforce compliance. This guidance document discusses, among other things:

- Definitions
- FDA's interpretation of and compliance policy for the label requirement in section 903(a)(2)(C) of the FD&C Act
- Which activities subject vape shops to certain requirements of the FD&C Act
- Limited circumstances under which FDA does not intend to enforce compliance[4]

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

[2] While this guidance discuses vape shops, FDA considers it to apply to any establishment that performs the described activities for tobacco products, such as retail stores that sell waterpipes or pipes.

[3] See FDA's final rule, Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act (81 FR 28973, May 10, 2016) (the deeming rule), available at https://www.gpo.gov/fdsys/pkg/FR-2016-05-10/pdf/2016-10685.pdf.

[4] The compliance policies described in this guidance are separate and apart from the compliance policies described in the preamble to the deeming rule. For more information on those policies, please refer to the preamble of the

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.

II. BACKGROUND

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111-31) into law. The Tobacco Control Act granted FDA authority to regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, roll-your-own tobacco (RYO), 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 tobacco product to be subject to FDA's tobacco product authority under chapter IX of the FD&C Act (section 901(b) of the FD&C Act). On May 10, 2016, FDA issued the deeming rule extending FDA's tobacco product authority to all products, other than accessories of newly deemed products, that meet the statutory definition of tobacco product, including electronic nicotine delivery systems (ENDS) (81 FR 28973) ("the deeming rule").[5]

Retail establishments that engage in certain activities may also be subject to particular requirements of the FD&C Act that apply to tobacco product manufacturers and to establishments that engage in the manufacture, preparation, compounding, or processing of tobacco products. These activities may include modifying a product so that it is a "new tobacco product" subject to premarket review. As explained in the deeming rule, the FD&C Act authorizes FDA to regulate the manufacture of new tobacco products including those manufactured at the retail level. This is important to FDA's ability to protect the public health because products manufactured at the retail level pose many of the same risks as those manufactured upstream and possibly additional risks related to the lack of standard manufacturing practices and controls (81 FR 28973 at 29044).

A. Section 904 of the FD&C Act

deeming rule as well as to the guidances for industry on *Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule* (Revised November 2017) (the compliance dates announced in that guidance supersede the compliance dates included in any other guidance issued prior to it), *Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments* (Revised December 2017), *Listing of Ingredients for Tobacco Products* (Revised April 2018), and *Health Document Submission Requirements for Tobacco Products* (Revised October 2017).

[5] Deeming rule (81 FR 28973)

Section 904(a) of the FD&C Act sets forth certain requirements for tobacco product manufacturers.[6] These requirements include:

- Ingredient listing (section 904(a)(1) of the FD&C Act);
- Reporting of harmful or potentially harmful constituents (HPHCs) (section 904(a)(3) of the FD&C Act); and
- Tobacco health document submission (section 904(a)(4) of the FD&C Act).

Section 904(c) of the FD&C Act requires the submission of information when changing any, or the quantity of any, additive in an existing tobacco product or introducing into interstate commerce a tobacco product that was not previously on the market.[7]

As explained in the deeming rule, the requirements of section 904(a) and (c) of the FD&C Act apply to manufacturers of the newly deemed products, including ENDS retail establishments that mix or prepare e-liquids or create or modify aerosolizing apparatus, also referred to as e-cigarettes, for sale or distribution (81 FR 28973 at 29046).

B. Section 910 of the FD&C Act

Under section 910 of the FD&C Act, "new tobacco products" are subject to premarket review.[8] As explained in the deeming rule, ENDS retailers engaged in mixing or preparing e-liquids or creating or modifying aerosolizing apparatus, also referred to as e-cigarettes, are required to obtain premarket authorization for each new tobacco product that they prepare for sale or distribution to consumers (81 FR 28973 at 29044). If a tobacco product that is required to have marketing authorization is marketed without authorization, the product is adulterated under section 902(6)(A) of the FD&C Act.

C. Section 905 of the FD&C Act

Additionally, section 905(b) of the FD&C Act requires that "every person who owns or operates any establishment in any State engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products" register with FDA the name, places of business, and all establishments engaged in these activities owned or operated by that person. For purposes of section 905, "manufacture, preparation, compounding, or processing" includes "repackaging, or otherwise changing the container, wrapper, or labeling of any tobacco product package in furtherance of the distribution of the tobacco product from the original place of manufacture to the person who makes the final delivery or sale to the ultimate consumer or

[6] The requirements in section 904(a) of the FD&C Act also apply to importers.

[7] For more information, please see the guidances for industry *Listing of Ingredients for Tobacco Products* (Revised April 2018) and *Health Document Submission Requirements for Tobacco Products* (Revised October 2017).

[8] The term *new tobacco product* is defined in section 910(a)(1) of the FD&C Act and set out for convenience in section III of this guidance.

user." Following the initial registration, every person must register annually by December 31 of each year.

Section 905(i)(1) of the FD&C Act requires that all registrants "shall, at the time of registration . . . . file with [FDA] a list of all tobacco products which are being manufactured, prepared, compounded, or processed by that person for commercial distribution," along with certain accompanying information, including all labeling. In addition, section 905(i)(3) of the FD&C Act requires that certain changes in the product list be submitted biannually.[9] As explained in the deeming rule, if an ENDS retail establishment engages in the manufacture, preparation, compounding, or processing of tobacco products, it is required to register and list its products with FDA in accordance with section 905 of the FD&C Act (81 FR 28973 at 29046).

III. DEFINITIONS

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

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 tobacco product; or

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

(21 CFR 1100.3)

"Composition," as used in this definition, means the manner in which the materials, including, for example, ingredients, additives, and biological organisms (e.g., micro-organisms added for fermentation in smokeless products), are arranged and integrated.

Examples of objects used with ENDS (including e-cigarettes) that would likely be considered accessories include screwdrivers and lanyards.

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.

[9] For more information, please see Guidance for Industry: Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments (Revised December 2017).

Component or part excludes anything that is an accessory of a tobacco product.

(21 CFR 1100.3)

The following is a nonexhaustive list of examples of components or parts of ENDS (including e-cigarettes): e-liquids, atomizers, batteries (with or without variable voltage), cartomizers (atomizer plus replaceable fluid-filled cartridge), digital display/lights to adjust settings; clearomizers (refillable e-liquid cartridges with built-in atomizer and wicking system), tank systems, flavors, bottles that contain e-liquids, and programmable software.

For purposes of this guidance, FDA is using the terms component and part interchangeably and without emphasizing a distinction. FDA may clarify distinctions between component and part in the future.

New tobacco product means:

(A) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or
(B) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.

(Section 910(a)(1) of the FD&C Act (21 U.S.C. 387j(a)(1)))

Tobacco product is defined in section 201(rr) of the FD&C Act, which states in relevant part:

(1) The term "tobacco product" means 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)."
(2) The term "tobacco product" does not include 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].[10]

IV. DISCUSSION

A. FDA's Interpretation of and Compliance Policy for the Requirement Under Section 903(a)(2)(C) that the Label Include an Accurate Statement of the Percentage of Foreign and Domestic Grown Tobacco

[10] Note that this definition includes accessories and components and parts of tobacco products, whether they are made or derived from tobacco, and whether they are sold or distributed as finished tobacco products. However, as explained above, accessories of tobacco products subject to the deeming rule are explicitly excluded from the rule's deeming provision. Thus, although they meet the definition of tobacco product, such accessories are not currently subject to regulation under chapter IX of the FD&C Act.

Under section 903(a)(2)(C) of the FD&C Act, a tobacco product in package form is misbranded if its label does not include an accurate statement of the percentage of tobacco used in the product that is foreign-grown and domestic-grown. FDA interprets this provision as applying only to tobacco products that are made or derived from tobacco. Therefore, tobacco products (including components, parts, and accessories) that are not made or derived from tobacco, such as cigarette filters, hookah pipes, and ENDS batteries, would not be required to bear an accurate statement of the percentage of foreign and domestic grown tobacco used in those products. Additionally, at this time, FDA does not intend to enforce the requirement in section 903(a)(2)(C) of the FD&C Act that tobacco products in package form bear a label with an accurate statement of the percentage of foreign- and domestic-grown tobacco for those products that are made or derived from tobacco, including tobacco-derived liquid nicotine, e-liquid made or derived from tobacco, cigars, smokeless tobacco, and waterpipe tobacco. FDA is providing this compliance policy because it recognizes the current scientific and technical difficulties, in many circumstances, of quantifying the percentage of foreign and domestic tobacco used in these products. For example, these difficulties include lot-to-lot variation in tobacco, difficulties in discerning tobacco source percentages after mixing with other ingredients, and limitations on access to proprietary ingredient information from a supplier. To the extent that the circumstances relevant to compliance with this requirement change in the future, FDA intends to reassess this policy.

B. Vape Shop Activities and the Requirements of the FD&C Act

Vape shops that are tobacco product manufacturers are subject to the requirements in section 904(a) and (c) the FD&C Act, including the requirements to provide ingredient listings, report HPHCs, and submit health documents. Vape shops that modify a product so that it is a new tobacco product as defined in section 910 are required to comply with the premarket authorization requirements. Finally, vape shops that are engaged in the manufacture, preparation, compounding, or processing of tobacco products are required to comply with establishment registration and product listing in accordance with section 905 of the FD&C Act. Below, we discuss whether vape shops engaged in certain activities are subject to the requirements described above and, if so, under what circumstances FDA generally does not intend to enforce compliance.

1. Activities That Modify a Product

a. Modifications Outside the Marketing Authorization Order

Generally, new tobacco products must obtain premarket authorization through the premarket tobacco application (PMTA), substantial equivalence (SE), or substantial equivalence exemption (SE exemption) pathway. Section 910(a)(2) of the FD&C Act. A vape shop's modifying a product outside the marketing authorization order for that product would generally result in a new tobacco product for which the vape shop is required to seek premarket authorization (see section 910). Additionally, the vape shop generally would be required to comply with the ingredient listing, HPHC reporting, and health document submission requirements in section 904 of the FD&C Act as well as registration and listing in accordance with section 905 of the FD&C Act.

b. Modifications to Products on the Market as of August 8, 2016, that do not yet have a Marketing Authorization Order

For products that do not yet have marketing authorization orders, a vape shop's modifying a product would generally result in a new tobacco product for which the vape shop is required to seek premarket authorization (see section 910). Additionally, the vape shop generally would be required to comply with the ingredient listing, HPHC reporting, and health document submission requirements in section 904 of the FD&C Act as well as registration and listing in accordance with section 905 of the FD&C Act. However, if an original manufacturer has provided specifications[11] for the tobacco product, FDA does not intend to enforce these requirements if the vape shop modifies a tobacco product consistent with the specifications provided by the original manufacturer. FDA is providing this compliance policy because FDA does not expect these modifications to alter the performance of the tobacco product as described or intended by original manufacturers.

c. Refilling *Open ENDS*

If not already covered by a marketing authorization order, a vape shop's refilling an open ENDS product[12] would generally result in a new tobacco product for which the vape shop is required to seek premarket authorization. Additionally, the vape shop generally would be required to comply with the ingredient listing, HPHC reporting, and health document submission requirements in section 904 of the FD&C Act as well as registration and listing in accordance with section 905 of the FD&C Act. However, if the vape shop does not make any further modifications to the product or any modifications to the e-liquid (e.g., mixing) before, during, or after the refill, that are either outside the marketing authorization order or, if there is no marketing authorization order, inconsistent with the original manufacturer specifications, then FDA does not intend to enforce these requirements.

d. Examples[13]

If a vape shop performs the following activities in the examples below, the vape shop would be: modifying a product (and thus required to seek premarket authorization pursuant to section 910 of the FD&C Act); a tobacco product manufacturer (and thus required to submit ingredient lists,

[11] For the purposes of this guidance, a manufacturer's specification includes instructions provided with the product, or other apparent markings or information on the product or its package noting specifications. For example, an original coil included in an ENDS apparatus may be marked with wattage compatibility or ohm resistance. Alternatively, an ENDS apparatus package may list ENDS components or parts, by model number or other criteria (e.g., wattage), that the original manufacturer represents would be compatible with the product.

[12] For the purposes of this guidance, the term *open ENDS* refers to those ENDS that include a refillable e-liquid reservoir (previously referred to as an open system ENDS).

[13] The examples provided are not intended to be an exhaustive list and any specific modifications will be considered on a case-by-case basis.

HPHC reports, and health documents pursuant to section 904 of the FD&C Act); and engaged in the manufacture, preparation, compounding, or processing of tobacco products (and thus required to register and list pursuant to section 905 of the FD&C Act):

- A vape shop that modifies a *closed ENDS*[14] to refill it for a customer.
- A vape shop that repairs and modifies an atomizer head, and the modification is outside the marketing authorization order.
- A vape shop that replaces the coils in an ENDS product that was on the market as of August 8, 2016 but that does not yet have a marketing authorization order with coils that have a different ohm[15] and/or wattage rating.[16] If there are no specifications from the original manufacturer, then the vape shop would not be subject to the compliance policy described above (in section IV.B.1.b).
- A vape shop that assembles a custom final product[17] from components or parts sold individually or from multiple pre-built kits, that were on the market as of August 8, 2016 but that do not yet have marketing authorization orders.[18]

2. Activities That Do Not Modify the Product

If a vape shop does not modify the tobacco product, the shop is not required to obtain premarket authorization. To the extent that the vape shop is required to comply with the ingredient listing, HPHC reporting, and health document submission requirements in section 904 of the FD&C Act

[14] For the purposes of this guidance, the term *closed ENDS* refers to those ENDS that include an e-liquid reservoir that is not refillable (previously referred to as a closed system ENDS).

[15] Ohms are the units used to measure and describe electrical resistance.

[16] Wattage rating is a rating expressing maximum power that a device can safely handle continuously.

[17] For the purposes of this guidance, a *custom* final product is one that is assembled from multiple off-the-shelf components or parts where the assembled product is not covered by a marketing authorization order, or if the components or parts do not yet have marketing authorization orders but were on the market as of August 8, 2016, the assembled product is inconsistent with the original manufacturer's specifications. For example, if an ENDS retailer assembled a product from an off-the-shelf tank, battery, and atomizer, none of which have a marketing authorization order but all of which have been on the market as of August 8, 2016, if the assembled product is inconsistent with the original manufacturer's specifications and is not covered by a marketing authorization order, it is a *custom* final product. A *custom* final product would not include a final product assembled from components and parts from multiple pre-built kits or sold individually if the final assembled product consists of components and parts that are also available packaged together in a single pre-built ENDS kit covered by a marketing authorization order or that was on the market as of August 8, 2016.

[18] If a vape shop assembled a product from multiple off-the-shelf components or parts that were on the market as of August 8, 2016 (but that do not yet have marketing authorization orders), consistent with the original manufacturer's specifications, that assembled product would not be a custom final product. Additionally, the vape shop would be subject to the compliance policy described above (in section IV.B.1.b).

as well as registration and listing in accordance with section 905 of the FD&C Act, FDA does not intend to enforce these requirements if the tobacco product is not modified.

If a vape shop performs the following activities in the examples below, the vape shop would not be required to seek premarket authorization; submit ingredient lists, HPHC reports, and health documents in accordance with section 904 of the FD&C Act; or register and list in accordance with section 905 of the FD&C Act:

- A vape shop that demonstrates the use of an ENDS product without assembling the product, including by providing instruction designed to assist users on the correct use of the product.[19]

- A vape shop that explains how to charge the battery or fill the ENDS tank, or how to turn on the ENDS device

If a vape shop performs the activities in the examples below, the vape shop would not be required to seek premarket authorization. To the extent that the vape shop would be a tobacco product manufacturer (and thus required to submit ingredient lists, HPHC reports, and health documents pursuant to section 904 of the FD&C Act) and engaged in the manufacture, preparation, compounding, or processing of tobacco products (and thus required to register and list pursuant to section 905 of the FD&C Act), FDA does not intend to enforce those requirements:

- A vape shop that maintains an ENDS product by cleaning or tightening fixtures (e.g., screws)

- A vape shop that replaces the coils in an ENDS product with identical coils from the same manufacturer (e.g., same ohm and wattage rating)

- A vape shop that assembles a final product from the components or parts packaged together in a pre-built ENDS kit or from components and parts sold individually or from multiple kits if the final assembled product consists of components and parts that are also available packaged together in a single pre-built ENDS kit.

[19] Note, however, that permitting a potential purchaser to consume the product as part of a demonstration or explanation would be a violation of the ban on free samples under §1140(d)(1); it would not be a violation of the ban if the consumer has already purchased the product.