Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 1–877–287–1373, *AskCTP@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Compliance Policy for Required Warning Statements on Small-Packaged Cigars.''

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) into law. The Tobacco Control Act granted FDA the authority to regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, roll-your-own 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 all other products that meet the statutory definition of a tobacco product to be subject to Chapter IX of the FD&C Act (section 901(b) of the FD&C Act). On May 10, 2016, FDA issued that rule, extending FDA's tobacco product authority to cigars, among other products (81 FR 28974). Among the requirements that now apply to cigars are health warning statements prescribed under section 906(d) of the FD&C Act, which permits restrictions on the sale and distribution of tobacco products that are ''appropriate for the protection of the public health.'' The rule specifies the health warning statements that must be displayed on cigar packaging and where those statements must be placed, among other requirements.

The draft guidance discusses FDA's compliance policy for cigars with packaging too small or otherwise unable to accommodate the warning statements and specifications required under the regulation.

II. Significance of Draft Guidance

FDA is issuing this draft guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on its compliance policy for cigars in small packaging. 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.

III. Paperwork Reduction Act of 1995

This draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR part 1143 have been approved under 0910–0768.

IV. Electronic Access

Persons with access to the Internet may obtain an electronic version of the guidance at either *http://www.regulations.gov* or *http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm.*

Dated: January 11, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–00855 Filed 1–13–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–0120]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry entitled ''Interpretation of and Compliance Policy for Certain Label Requirement; Applicability of Certain Federal Food, Drug, and Cosmetic Act Requirements to Vape Shops.'' This draft guidance provides FDA's interpretation of, and a compliance policy for, the requirement that the label of tobacco products contain an accurate statement of the percentage of foreign and domestic grown tobacco under the Federal Food, Drug, and Cosmetic Act (the FD&C Act). This draft guidance document is also intended to assist retailers who sell newly deemed products by explaining whether engaging in certain activities subjects such establishments to additional requirements of the FD&C Act and the limited circumstances under which FDA does not intend to enforce compliance.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 16, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–D–0120 for ''Interpretation of and Compliance Policy for Certain Label Requirement; Applicability of Certain Federal Food, Drug, and Cosmetic Act Requirements to Vape Shops.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov*

or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Katherine Collins, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002, 1–877–287–1373, email: *AskCTP@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance for industry entitled ''Interpretation of and Compliance Policy for Certain Label Requirement; Applicability of Certain Federal Food, Drug, and Cosmetic Act Requirements to Vape Shops.''

This draft guidance document, when finalized, will provide FDA's interpretation of, and a compliance policy for, the label requirement under section 903(a)(2)(C) of the FD&C Act (21 U.S.C. 387c(a)(2)(C)). This draft guidance document, when finalized, is also intended to assist retailers who sell newly deemed products by explaining whether engaging in certain activities subjects such establishments to additional requirements of the FD&C Act and the limited circumstances under which FDA does not intend to enforce compliance.

The Family Smoking Prevention and Tobacco Control Act (Pub. L. 111–31) (Tobacco Control Act), enacted on June 22, 2009, amends section 904 of the FD&C Act (21 U.S.C. 387d) and provides FDA with the authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

Cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco were immediately covered by FDA's tobacco product authorities in chapter IX of the FD&C Act, when the Tobacco Control Act went into effect. As for other types of tobacco products, section 901(b) of the FD&C Act (21 U.S.C. 387a(b)) grants FDA authority to deem those products subject to chapter IX of the FD&C Act. Under that authority, FDA issued a rule deeming all other products that meet the statutory definition of ''tobacco product,'' set forth in section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)), except for accessories of those products, as subject to chapter IX of the FD&C Act (81 FR 28974). FDA published the final rule on May 10, 2016, and it became effective on August 8, 2016.

Section 903(a)(2)(C) of the FD&C Act provides that a tobacco product in package form is misbranded unless its label contains ''an accurate statement of the percentage of tobacco used in the product that is domestically grown tobacco and the percentage that is foreign grown tobacco.'' The draft guidance provides FDA's interpretation of, and a compliance policy for, this label requirement.

Retail establishments, such as vape shops, which engage in certain activities may also be subject to certain 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 product. These activities may also include modifying a product so that it is a new tobacco product requiring compliance with the premarket authorization requirements. This draft guidance explains which activities subject vape shops to these FD&C Act requirements and the limited circumstances under which FDA does not intend to enforce compliance.

II. Significance of Guidance

FDA is issuing this draft guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA. 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.

III. Electronic Access

Persons with access to the Internet may obtain an electronic version of the draft guidance at either *https://www.regulations.gov* or *http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm.*

Dated: January 9, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–00773 Filed 1–13–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–0114]

Referencing Approved Drug Products in Abbreviated New Drug Application Submissions; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled