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a draft guidance for industry entitled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
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The draft guidance discusses FDA’s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
that the label of tobacco products
contain an accurate statement of the
percentages 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This draft guidance document is also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

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This draft guidance also refers to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 0910−0788.

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/RulesRegulations Guidance/
default.htm.


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
percentages 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 authorizations 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