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Submit written requests for single copies of the draft guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm.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

''Referencing Approved Drug Products in ANDA Submissions.'' Any person is permitted to submit an abbreviated new drug application (ANDA) in order to seek approval to market a generic version of a previously approved drug product. The purpose of this guidance is to provide information to potential applicants on how to identify a reference listed drug (RLD), reference standard, and the basis of submission in an ANDA submission.

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 on 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 March 20, 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–0114 for ''Referencing Approved Drug Products in ANDA Submissions.'' 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 Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Gail Schmerfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–9291, *gail.schmerfeld@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Referencing Approved Drug Products in ANDA Submissions.'' To obtain approval of an ANDA submitted under section 505(j) of the FD&C Act (21 U.S.C. 355(j)), an ANDA applicant generally must show, among other things, that the proposed generic drug has the same active ingredient(s), conditions of use, route of administration, dosage form, strength, and, with certain permissible differences, labeling as the specific listed drug referred to in the ANDA, *i.e.,* the RLD. Under section 505(j)(2)(A)(iv) of the FD&C Act, the ANDA applicant also must demonstrate that the proposed generic drug is bioequivalent to the RLD and, if in vivo bioequivalence studies are required for approval of the ANDA, the applicant must use the reference standard selected by FDA in such testing (21 CFR 314.3(b)). Further, under section 505(j)(2)(A)(vi) of the FD&C Act, a generic drug must meet the same high standards of quality and manufacturing as drug products approved under section 505(c) of the FD&C Act.

This guidance provides information to potential applicants on how to identify a ''reference listed drug,'' ''reference standard,'' and the ''basis of submission'' in ANDA submissions. A variety of factors has led to confusion among stakeholders on what these terms mean and how an ANDA applicant should use them. These factors include the discontinued marketing of many approved drug products and FDA's identification of reference standards with the RLD symbol (''+'') in the printed version, and under the ''RLD'' column in the electronic version, of FDA's ''Approved Drug Products with Therapeutic Equivalence Evaluations'' (the ''Orange Book''). This guidance is intended to address this confusion by explaining what these terms mean and clarifying the differences among them. This guidance provides

recommendations on how to accurately use these terms in an ANDA, how persons can request FDA designation of an RLD, and how persons can request FDA selection of a reference standard.

This draft guidance is being issued 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 Referencing Approved Drug Products in ANDA Submissions. 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.

II. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: January 11, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–00820 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–2016–N–4662]

Public Hearing: Strategic Partnerships To Enhance the Safety of Imported Foods: Capacity Building, Risk-Based Decisionmaking, Recognition of Commodity Food Control Programs, and Systems Recognition; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing a public hearing regarding FDA initiatives for enhancing the safety of foods (for humans and animals) imported into the United States. The hearing will focus on partnerships to improve safety capabilities through capacity building; partnerships that incorporate information from private entities and foreign competent authorities to inform risk-based decisionmaking; partnerships that recognize commodity-specific export programs; and partnerships that recognize the robustness of a nation's entire food safety system. In addition, we are seeking information from a variety of viewpoints, including from competent authorities in other countries and from private entities, to help inform FDA regarding risk-based decisionmaking, commodity-specific export control programs in other countries, and systems recognition.

DATES: See ''How to Participate in the Hearing'' in the **SUPPLEMENTARY INFORMATION** section of this document for dates and times of the public meetings, closing dates for advance registration, requesting special accommodations due to disability, closing date to submit comments to the docket, and other information regarding meeting participation.

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–2016–N–4662 for ''Public Hearing: Strategic Partnerships to Enhance the Safety of Imported Foods: Capacity Building, Risk-Based Decisionmaking, Recognition of Commodity Food Control Programs, and Systems Recognition.'' 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.'' We will review this copy, including the claimed confidential information, in our 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.

FOR FURTHER INFORMATION CONTACT: Wade Woolfolk, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS–550), 5001