copies to the Dockets Management Staff. If you do not wish your name and contact information 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 the 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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lauren Tesh Hotaki, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, Fax: 301–847–8533, *AMDAC@fda.hhs.gov;* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The committee will discuss supplemental new drug application (sNDA) 208215, supplement 12, DESCOVY (emtricitabine 200 milligrams (mg) and tenofovir alafenamide 25 mg tablets), submitted by Gilead Sciences, Inc., proposed for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV–1 infection among individuals who are HIV-negative and at risk for HIV.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see the **ADDRESSES** section) on or before July 24, 2019, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before July 16, 2019. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by July 17, 2019.

Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Lauren Tesh Hotaki (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 18, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–13355 Filed 6–21–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–1163]

Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs; 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 final guidance for industry entitled ''Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs.'' This guidance outlines the requirements and recommendations for various types of submissions of promotional materials for prescription drugs and biological products, including the specific formats needed for use in the electronic common technical document (eCTD) as well as non-eCTD and non-electronic formats. This guidance finalizes the draft guidance issued in April 2015.

DATES: The announcement of the guidance is published in the **Federal Register** on June 24, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time 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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, 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–2015–D–1163 for ''Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs.'' 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 Dockets Management Staff 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 Dockets Management Staff. 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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this 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; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, 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 guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding prescription human drugs: Kemi Asante, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3374, Silver Spring, MD 20993–0002, 301–796–1200.

Regarding prescription human biological products: Stephen Ripley, Center for Biologics Evaluation and Research Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs.'' Portions of this guidance are intended to be used in conjunction with the guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications'' (eCTD Guidance) and the specifications for module 1.[1] This guidance outlines the requirements and recommendations for manufacturers, packers, and distributors (firms) that may either be the applicant or acting on behalf of the applicant, to make submissions pertaining to promotional materials for human prescription drugs (drugs) to the Office of Prescription Drug Promotion in the Center for Drug Evaluation and Research (CDER) and the Advertising and Promotional Labeling Branch in the Center for Biologics Evaluation and Research (CBER). References to ''drugs'' in this guidance also include human biological products that fall within the definition of ''drug'' under section 201(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321(g)).

This guidance describes various types of regulatory submissions of promotional materials that firms submit to CDER and CBER, along with general considerations and formats for such submissions. For example, the guidance describes the various types of voluntary submissions (*e.g.,* launch and non-launch voluntary submissions of draft promotional materials for comments) and required submissions of promotional labeling and advertising materials (*e.g.,* fulfillment of the regulatory requirements for postmarketing submissions of promotional materials and submission of promotional materials for accelerated approval products). In addition, this guidance discusses specific aspects of the content and format for submitting promotional materials in paper copy and electronic format, including how to submit promotional materials electronically in module 1 of the eCTD using version 3.3 or higher of *the us-regional-backbone* file. This guidance provides recommendations for what to include with each type of submission and the number of copies to include if it is a paper submission. This guidance provides recommendations for

[1] The eCTD Guidance is available on the FDA website at *https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM333969.pdf.* The current version of the specification for industry entitled *The eCTD Backbone Files Specification for Module 1* provides additional information and is available at *https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/UCM163552.pdf.*

presentation considerations such as appearance, layout, format, and visible impression of promotional materials submitted for all promotional submission types.

This guidance also provides instructions on how to submit promotional labeling and advertising materials to FDA electronically in eCTD format. It explains that for submissions of promotional materials that fall within the scope of section 745A(a) of the FD&C Act (21 U.S.C. 379k–1), such submissions must be made in the electronic format specified by FDA in this guidance and the guidance for industry ''Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications'' (eCTD Guidance), beginning no earlier than 24 months after this guidance is issued. Specifically, (1) postmarketing submissions of promotional materials using Form FDA 2253 (required by 21 CFR 314.81(b)(3)(i) and 21 CFR 601.12(f)(4)), and (2) submissions of promotional materials for accelerated approval products (required by section 506(c)(2)(B) of the FD&C Act (21 U.S.C. 356(c)(2)(B)) and §§ 314.550 and 601.45) and other products where such submissions are required for approval, fall within the scope of section 745A(a) and are, therefore, subject to the mandatory electronic submission requirement. The implementation date for the mandatory electronic submission is June 24, 2021. When the implementation date for the mandatory electronic submission requirement takes effect for these types of submissions, they will only be accepted in eCTD format using version 3.3 or higher of the *us-regional-backbone* file. The guidance also provides that, while only promotional submissions that fall under section 745A(a) of the FD&C Act will be required to be submitted electronically no sooner than 24 months after this guidance is issued, firms may choose—and are strongly encouraged, but not required—to submit electronically the other types of promotional submissions discussed in this guidance.

In the **Federal Register** of April 22, 2015 (80 FR 22529), FDA announced the availability of the draft guidance of the same title. FDA received several comments regarding the need to provide clarity on submission expectations and technical aspects of electronic submissions, and those comments were considered as the guidance was finalized. A summary of changes made in this guidance include: (1) Changes to provide greater clarity on submission expectations, (2) changes to provide greater clarity around technical aspects related to electronic submissions, (3) changes to create consistency between terms used in the final guidance and the eCTD guidance, (4) changes to address unexpected technical issues that have been discovered since the eCTD software launched, and (5) changes to encourage the submission of a compact disc copy of paper submissions. In addition, editorial and formatting changes were made to improve clarity.

This guidance is being issued under section 745A(a) of the FD&C Act; wherein Congress granted FDA authorization to require that submissions under section 505(b), (i), or (j) of the FD&C Act (21 U.S.C. 355(b), 21 U.S.C. 355(i), or 21 U.S.C. 355(j), respectively) and submissions under section 351(a) or (k) of the Public Health Service Act (PHS Act); be submitted in an electronic format specified by FDA through guidance. Accordingly, insofar as this guidance requires that submissions under section 505(b), (i), or (j) of the FD&C Act and submissions under section 351(a) or (k) of the PHS Act be submitted in electronic format specified by FDA, this document is not subject to the usual restriction in FDA's good guidance practice regulations that guidances not establish legally enforceable responsibilities. (See 21 CFR 10.115(d).) Therefore, the portion of this guidance that establishes the requirement for electronic submissions under section 745A(a) of the FD&C Act has binding effect, as indicated by the use of the words *must, shall, or required*. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in this guidance was approved under OMB control number 0910–0870.

This guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR 202.1, including voluntary requests for advisory comments,[2] resubmissions, and amendments for advertisements, have been approved under OMB control number 0910–0686; the collections of information in 21 CFR 601.45 (presubmission of promotional materials for accelerated approval products under part 601) have been approved under OMB control number 0910–0338; the collections of information for Form FDA 2253 and the presubmission of promotional materials for accelerated approval products under part 314 have been approved under OMB control number 0910–0001.

[2] Reference in this guidance to the voluntary request for advisory comment(s) on proposed promotional materials by firms is distinct from and not to be confused with the process identified in 21 CFR 10.85.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *https://www.regulations.gov*.

Dated: June 18, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–13350 Filed 6–21–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–2836]

Allergenic Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Allergenic Products Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues.

DATES: The meeting will be held on September 13, 2019, from 8:30 a.m. to 4:30 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

For those unable to attend in person, the meeting will also be webcast and will be available at the following link: *https://collaboration.fda.gov/apac091319/.*

FOR FURTHER INFORMATION CONTACT: CAPT Serina Hunter-Thomas or Ms.