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 fdaomha@fda.hhs.gov or 301–796–1325.

FDAC omes 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.

FDAC omes 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).
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 Fishe rs 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 Fishe rs 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.


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

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 guidelines 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, 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.

III. Electronic Access


Dated: June 18, 2019.

Lowell J. Schiller,
Principal Associate Commissioner for Policy.

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.

For those unable to attend in person, the meeting will also be webcast and will be available at the following link: https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.

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