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In the **Federal Register** of April 22, 2015 (80 FR 22529), FDA announced the availability of the draft guidance of the same title.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.

Monique Hill, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6338, Silver Spring, MD 20993–0002, 240–402–5771, *serina.hunter-thomas@fda.hhs.gov* or 301–796–4620, *monique.hill@fda.hhs.gov* respectively, 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 Agency'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. For those unable to attend in person, the meeting will also be available via Webcast. The Webcast will be available at the following link: *https://collaboration.fda.gov/apac091319/.*

SUPPLEMENTARY INFORMATION:

Agenda: On September 13, 2019, the Center for Biologics Evaluation and Research's (CBER) Vaccines and Related Biological Products Advisory Committee (VRBPAC) will meet in open session to discuss and make recommendations on the safety and efficacy of Peanut [*Arachis hypogaea*] Allergen Powder manufactured by Aimmune Therapeutics, Inc, indicated for treatment to reduce the risk of anaphylaxis after accidental exposure to peanut in patients aged 4 to 17 years with a confirmed diagnosis of peanut allergy.

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: On September 13, 2019, from 8:30 a.m. to 4:30 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before September 6, 2019. On September 13, 2019, oral presentations from the public will be scheduled between approximately 1 p.m. to 2 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 August 29, 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 August 30, 2019.

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

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 Serina Hunter-Thomas 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. 2019–13354 Filed 6–21–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0945–0002]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before July 24, 2019.

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 795–7714. When submitting comments or requesting information, please include the document identifier 0990–New–30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Health Information Privacy and Civil Rights/Conscience and Religious Freedom Discrimination Complaint.

Type of Collection: Revision.

OMB No. 0945–0002.

Abstract: The Office for Civil Rights is seeking a revision on an approval for a 3-year clearance on a previous collection. Individuals may file written or electronic complaints with the Office for Civil Rights when they believe they have been discriminated against by programs or entities that receive Federal financial assistance from the Health and Human Service or if they believe that their right to the privacy of protected health information freedom has been violated. Annual Number of Respondents frequency of submission is record keeping and reporting on occasion.