ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by February 16, 2016.

ADDRESSES: Submit written comments on the collection of information by email to *OIRA_submission@omb.eop.gov* Attn: OMB Desk Officer for ACL, or by fax 202–395–6974, Office of Information and Regulatory Affairs, OMB.

FOR FURTHER INFORMATION CONTACT: Lori Stalbaum at (202) 357–3452, or *lori.stalbaum@acl.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, ACL has submitted the following proposed collection of information to OMB for review and clearance.

Describe Collection of Information

ACL is requesting to continue an existing approved collection of information for semi-annual and final reports pursuant to the requirements of its discretionary grant programs. ACL estimates the burden of this collection of information as follows: *Frequency:* Semi-annually with the Final report taking the place of the semi-annual report at the end of the final year of the grant. *Respondents:* States, public agencies, private nonprofit agencies, institutions of higher education, and organizations including tribal organizations. *Estimated Number of Responses:* 600. *Total Estimated Burden Hours:* 12,000.

Dated: January 12, 2016.

Kathy Greenlee,

Administrator and Assistant Secretary for Aging.

[FR Doc. 2016–00762 Filed 1–14–16; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Navigating the Center for Drug Evaluation and Research: What You Should Know for Effective Engagement; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administrations (FDA) Center for Drug Evaluation and Research (CDER), is sponsoring a public workshop entitled ''Navigating CDER: What You Should Know for Effective Engagement.'' The purpose of this public workshop is to help the public and patient advocacy groups gain a better understanding of how to effectively engage CDER.

DATES: The public workshop will be held on March 31, 2016, from 8:30 a.m. to 5 p.m.

ADDRESSES: The public workshop will be held at FDA's White Oak campus, 10903 New Hampshire Ave., Building 31 (The Great Room A, B, and C), Silver Spring, MD 20993. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

FOR FURTHER INFORMATION CONTACT: Shawn Brooks, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 240–402–6509, email: *NAV-CDER@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is announcing a public workshop entitled ''Navigating CDER: What You Should Know for Effective Engagement.'' This public workshop is intended to enhance the public and advocacy groups' ability to effectively engage FDA's CDER. The presentations are intended to provide information on how best to interact with CDER. There will be an opportunity for questions and answers following each presentation.

Registration: There is no registration fee to attend the public workshop. Early registration is recommended because seating is limited, and registration will be on a first-come, first-served basis. There will be no onsite registration. Persons interested in attending this workshop must register online at *http://www.fda.gov/Drugs/NewsEvents/ucm472604.htm* before March 24, 2016. For those without Internet access, please contact Shawn Brooks (see **FOR FURTHER INFORMATION CONTACT**) to register.

If you need special accommodations due to a disability, please contact Shawn Brooks (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance.

Transcripts: A transcript of the workshop will be available for review at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and on the Internet at *http://www.regulations.gov* approximately 30 days after the workshop. Transcripts will also be available in either hard copy or on CD–ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at *http://www.fda.gov.*

Dated: January 8, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–00694 Filed 1–14–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Advisory Committee: Vaccines and Related Biological Products Advisory Committee, Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Vaccines and Related Biological Products Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Vaccines and Related Biological Products Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until December 31, 2017.

DATES: Authority for the Vaccines and Related Biological Products Advisory Committee will expire on December 31, 2017, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Sujata Vijh, Division of Scientific Advisors and Consultants, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6128, Silver Spring, MD 20993–0002, 240–402–7107, *Sujata.vijh@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3.65 and approval by the Department of Health and Human Services pursuant to 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the

Vaccines and Related Biological Products Advisory Committee. The committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Vaccines and Related Biological Products Advisory Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective vaccines and related biological products for human use and, as required, any other product for which the Food and Drug Administration has regulatory responsibility.

The Committee reviews and evaluates data concerning the safety, effectiveness, and appropriate use of vaccines and related biological products which are intended for use in the prevention, treatment, or diagnosis of human diseases, and, as required, any other products for which the Food and Drug Administration has regulatory responsibility. The Committee also considers the quality and relevance of FDA's research program which provides scientific support for the regulation of these products and makes appropriate recommendations to the Commissioner of Food and Drugs.

The Committee shall consist of a core of 15 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of immunology, molecular biology, rDNA, virology; bacteriology, epidemiology or biostatistics, vaccine policy, vaccine safety science, federal immunization activities, vaccine development including translational and clinical evaluation programs, allergy, preventive medicine, infectious diseases, pediatrics, microbiology, and biochemistry. Members will be invited to serve for overlapping terms of up to four years. Almost all non-Federal members of this committee serve as Special Government Employees. Ex Officio voting members one each from the Department of Health and Human Services, the Centers for Disease Control and Prevention, and the National Institutes of Health may be included. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting member who is identified with industry interests. There may also be an alternate industry representative.

The Commissioner or designee shall have the authority to select members of other scientific and technical FDA advisory committees (normally not to exceed 10 members) to serve temporarily as voting members and to designate consultants to serve temporarily as voting members when: (1) Expertise is required that is not available among current voting standing members of the Committee (when additional voting members are added to the Committee to provide needed expertise, a quorum will be based on the combined total of regular and added members), or (2) to comprise a quorum when, because of unforeseen circumstances, a quorum is or will be lacking. Because of the size of the Committee and the variety in the types of issues that it will consider, FDA may, in connection with a particular committee meeting, specify a quorum that is less than a majority of the current voting members. The Agency's regulations (21 CFR 14.22(d)) authorize a committee charter to specify quorum requirements. If functioning as a medical device panel, a non-voting representative of consumer interests and a non-voting representative of industry interests will be included in addition to the voting members.

Further information regarding the most recent charter and other information can be found at *http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/VaccinesandRelatedBiologicalProductsAdvisoryCommittee/ucm129571.htm* or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at *http://www.fda.gov/AdvisoryCommittees/default.htm.*

Dated: January 11, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2016–00675 Filed 1–14–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1203]

Agency Information Collection Activities; Proposed Collection; Comment Request; Information To Accompany Humanitarian Device Exemption Applications and Annual Distribution Number Reporting Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information to accompany humanitarian device exemption (HDE) applications and the collection of information regarding the annual distribution number (ADN).

DATES: Submit either electronic or written comments on the collection of information by March 15, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you