regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 collections of information in 21 CFR 601.12 and Form FDA 356h have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov*.

Dated: December 18, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–27569 Filed 12–21–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–6395]

Request for Nominations of Members for the Clinical Trials Transformation Initiative/Food and Drug Administration Patient Engagement Collaborative

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency), in collaboration with the Clinical Trials Transformation Initiative (CTTI), is requesting nominations of patient advocates interested in participating on the Patient Engagement Collaborative (PEC). The PEC will be an ongoing, collaborative forum coordinated through the Patient Affairs Staff, Office of Medical Products and Tobacco (OMPT), Office of the Commissioner, and will be hosted by CTTI. Through the PEC, the patient community and regulators will be able to discuss an array of topics regarding increasing meaningful patient engagement in medical product development and regulatory discussions at FDA. The activities of the PEC may include, but are not limited to, providing diverse perspectives on topics such as systematic patient engagement, transparency, and communication; providing considerations for implementing new strategies to enhance patient engagement at FDA; and proposing new models of collaboration in which patients and patient advocates are partners in certain aspects of the medical product development and FDA review process.

DATES: Nominations received by 11:59 p.m. Eastern Time on or before January 29, 2018, will be given first consideration for membership on the PEC. Nominations received after the submission deadline will be retained for future consideration.

ADDRESSES: All nominations should be submitted to the FDA's Patient Affairs Staff in the OMPT. Email nominations are preferred and should be submitted to *PatientEngagementCollaborative@fda.hhs.gov*. Though not required, it is appreciated if all nomination materials are compiled into a single PDF file and attached to the submission email. Nominations may also be submitted by mail or delivery service to Patient Affairs Staff, Office of Medical Products and Tobacco, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 1316, Silver Spring, MD 20993. Only complete applications, as described in section ''IV. Nomination Process'' of this document, will be considered.

FOR FURTHER INFORMATION CONTACT: Andrea Furia-Helms, Office of Medical Products and Tobacco, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 1316, Silver Spring, MD 20993, 301–796–8455, *PatientEngagementCollaborative@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background and Purpose

The CTTI is a public-private partnership co-founded by FDA and Duke University whose mission is to develop and drive adoption of practices that will increase the quality and efficiency of clinical trials. FDA and CTTI have long involved patients and considered patient perspectives in their work. Furthering the engagement of patients as valued partners across the medical product research and development continuum requires an open forum for patients and regulators to discuss and exchange ideas.

The PEC will be an ongoing, collaborative forum in which the patient community and regulators will discuss an array of topics regarding increasing patient engagement in medical product development and regulatory discussions at FDA. The PEC will be a joint endeavor between the CTTI and FDA. The activities of the PEC may inform relevant FDA and CTTI activities. The PEC is not intended to advise or otherwise direct the activities of either organization, and membership will not constitute employment by either organization.

The Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), section 1137, entitled ''Patient Participation in Medical Product Discussions,'' added section 569C to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–8c). This provision directs the Secretary of Health and Human Services to develop and implement strategies to solicit the views of patients during the medical product development process and consider the perspectives of patients during regulatory discussions. On November 4, 2014, FDA issued a **Federal Register** notice establishing a docket (FDA–2014–N–1698) for public commenters to submit information related to FDA's implementation of this provision (79 FR 65410). Upon review of the comments received, one common theme, among others, included establishing an external group to provide input on patient engagement strategies across FDA's Centers.

Recent legislation in both section 3001 of the 21st Century Cures Act and section 605 of the Food and Drug Administration Reauthorization Act of 2017 supports tools for fostering patient participation in the regulatory process.

The purpose of this notice is to announce that the nomination process for the PEC is now open, and to invite and encourage nominations by the submission deadline for appropriately qualified individuals. Self-nominations are accepted.

II. Criteria for Membership

The PEC will include up to 16 diverse representatives of the patient community. Selected members will include the following: (1) Patients who have personal disease experience; (2) caregivers who support patients, such as a parent, child, partner, other family member, or friend, and who have personal disease experience through this caregiver role; and (3) representatives from patient groups who, through their role in the patient group, have direct or indirect disease experience. Please note that for purposes of this activity, the term ''caregiver'' is not intended to include individuals who are engaged in caregiving as health care professionals; and the term ''patient group'' is used herein to encompass patient advocacy

organizations, disease advocacy organizations, voluntary health agencies, nonprofit research foundations, and public health organizations. The ultimate goal of the nomination and selection process is to identify individuals who can represent a collective patient voice for their patient community.

Selection criteria include the nominee's potential to meaningfully contribute to the activities of the PEC, ability to represent and express the patient voice for his or her constituency, ability to work in a constructive manner with involved stakeholders, and understanding of the clinical research enterprise. Consideration will also be given to ensuring the PEC includes diverse perspectives and experiences, including but not limited to, sociodemographic and disease experience diversity. It is anticipated that approximately half of the PEC membership will be selected from eligible CTTI member organizations and individuals, and half will be selected from other nominees. Members are required to be citizens and residents of the United States.

Financial and other conflicts of interest will not necessarily make nominees ineligible for membership in the PEC. However, nominees cannot be direct employees of the medical product development industry.

III. Responsibilities and Expectations

Meetings of the PEC will typically be held four times per year, either in-person (in the Washington, DC area) or by webinar, and additional meetings may be organized as needed. Accommodations will be made for members with special needs for travel or for participation in a meeting (*e.g.,* accommodations for physical mobility impairments, dietary restrictions, etc.). Nominations for PEC membership are encouraged for individuals of all racial, ethnic, sexual orientation, and cultural groups with and without disabilities. Travel support will be provided.

To help ensure continuity in its activities and organizational knowledge, the PEC will maintain staggered membership terms for patient community representatives. Membership terms are anticipated as 1- to 2-year appointments, and will be determined during the process of selecting members. Members may serve up to two terms, with the possibility of extensions.

Additional responsibilities and expectations are set forth in the Patient Engagement Collaborative Framework, which should be reviewed prior to submitting a nomination. The full text of the Patient Engagement Collaborative Framework is available at *https://www.ctti-clinicaltrials.org/framework-cttifda-patient-engagement-collaborative.*

IV. Nomination Process

Any interested person may nominate one or more qualified individuals for membership on the PEC. Self-nominations are also accepted.

Nominations should include the following: (1) A personal statement (maximum 800 words) from the nominee explaining his or her interest in becoming a member of the PEC; (2) a current, complete curriculum vitae or resume that shows relevant activities and experience; and (3) an optional letter of endorsement (maximum 800 words) from a patient group with which the nominee has worked closely on activities relevant to the PEC.

The personal statement and optional letter of endorsement (if provided) should emphasize information relevant to the criteria for membership described above. The letter may address topics such as the nominee's involvement in patient advocacy activities, experiences that stimulated an interest in participating in discussions about patient engagement in medical product development and regulatory decision-making, and other information that may be helpful in evaluating the nominee's qualifications as a potential member of the PEC.

Nominations must provide the nominee's contact information (phone and email preferred), as well as state that the nominee is aware of the nomination (unless self-nominated) and is willing to serve as a member of the PEC.

Additional information may be needed from nominees, including information relevant to understanding potential sources of conflict of interest, in which case nominees will be contacted directly.

Dated: December 15, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–27538 Filed 12–20–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1995–D–0288 (Formerly Docket No. 95D–0052)]

Chemistry, Manufacturing, and Controls Changes to an Approved Application: Certain Biological Products; 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 document entitled ''Chemistry, Manufacturing, and Controls Changes to an Approved Application: Certain Biological Products; Draft Guidance for Industry.'' The draft guidance is intended to assist applicants and manufacturers of certain licensed biological products in determining which reporting category is appropriate for a change in chemistry, manufacturing, and controls (CMC) information to an approved biologics license application (BLA). The draft guidance provides applicants and manufacturers general and administrative information on reporting and evaluating changes and recommendations for reporting categories based on a tiered-reporting system for specific changes. The draft guidance, when finalized, is intended to supersede the document entitled ''Guidance for Industry: Changes to an Approved Application: Biological Products'' dated July 1997 (July 1997 guidance).

DATES: Submit either electronic or written comments on the draft guidance by March 22, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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