Silver Spring, MD 20993–0002, 301–796–1546, *Kaetochi.Okemgbo@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

ENDEP (amitriptyline hydrochloride) oral concentrate, 40 mg/mL, is the subject of ANDA 085749, held by Hoffman-La Roche Inc., and initially approved on December 23, 1977. ENDEP (amitriptyline hydrochloride) oral concentrate, 40 mg/mL, is indicated for relief of symptoms of depression.

Hoffman-La Roche Inc. has never marketed ENDEP (amitriptyline hydrochloride) oral concentrate, 40 mg/mL. ANDA 085749 is listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Hyman, Phelps & McNamara, P.C., submitted a citizen petition dated January 11, 2022 (Docket No. FDA–2022–P–0068), under 21 CFR 10.30, requesting that the Agency determine whether ENDEP (amitriptyline hydrochloride) oral concentrate, 40 mg/mL, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that ENDEP (amitriptyline hydrochloride) oral concentrate, 40 mg/mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that ENDEP (amitriptyline hydrochloride) oral concentrate, 40 mg/mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of ENDEP (amitriptyline hydrochloride) oral concentrate, 40 mg/mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list ENDEP (amitriptyline hydrochloride) oral concentrate, 40 mg/mL, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to ENDEP (amitriptyline hydrochloride) oral concentrate, 40 mg/mL, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: September 14, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–20195 Filed 9–16–22; 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 Applications for New Members of the Clinical Trials Transformation Initiative/Food and Drug Administration Patient Engagement Collaborative

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for applications.

SUMMARY: The Food and Drug Administration (FDA or Agency), in collaboration with the Clinical Trials Transformation Initiative (CTTI), is requesting applications from patient advocates interested in participating on the Patient Engagement Collaborative (PEC). The PEC is an ongoing, collaborative forum coordinated through the Office of Patient Affairs, Office of Clinical Policy and Programs (OCPP), Office of the Commissioner at FDA, and is hosted by CTTI. Through the PEC, the patient community and regulators are able to discuss an array of topics regarding increasing meaningful patient engagement with diverse populations 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 patient and patient advocate perspectives are incorporated into general medical product development and regulatory processes.

DATES: Applications can be submitted starting at 11:59 p.m. eastern time on September 19, 2022. This announcement is open to receive a maximum of 75 applications. Applications will be accepted until 11:59 p.m. eastern time on October 19, 2022 or until 75 applications are received, whichever happens first.

ADDRESSES: All applications should be submitted to FDA's Office of Patient Affairs in OCPP. The preferred application method is via the online submission system provided by CTTI, available at *https://duke.qualtrics.com/jfe/form/SV_5nI1VVWVOaD59ky.* For those applicants unable to submit an application electronically, please call FDA's Office of Patient Affairs at 301–796–8460 to arrange for mail or delivery

service submission. Only complete applications, as described under section IV of this document, will be considered.

FOR FURTHER INFORMATION CONTACT: Wendy Slavit, Office of the Commissioner, Office of Clinical Policy and Programs, Office of Patient Affairs, Food and Drug Administration, 301–796–8460, *PatientEngagementCollaborative@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background and Purpose

The CTTI is a public-private partnership cofounded 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 diverse 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 is an ongoing, collaborative forum in which the patient community and regulators discuss an array of topics regarding increasing patient engagement in medical product development and regulatory discussions at FDA. The PEC is a joint endeavor between FDA and CTTI. 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. 112–14), 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. 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. After considering the comments, FDA formed the PEC in 2018 to discuss a variety of patient engagement topics. This group is consistent with additional legislation subsequently enacted in section 3001 of the 21st Century Cures Act (Pub. L. 114–255) and section 605 of the FDA Reauthorization Act of 2017 (Pub. L. 115–52), further supporting tools for fostering patient participation in the regulatory process.

The PEC currently has 16 members. To help ensure continuity in its activities and organizational knowledge, the PEC maintains staggered membership terms. As of fall 2022, eight members will complete a term and up to eight new members will be selected. The purpose of this notice is to announce that the application process for up to eight new members of the PEC is now open, and to invite and encourage applications by the submission deadline for appropriately qualified individuals.

II. Criteria for Membership

The PEC includes up to 16 diverse representatives of the patient community. Eight members from the previous application process will remain on the PEC. The current application process is to select up to eight new PEC members. 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/or (3) representatives of 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 healthcare 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 application and selection process is to identify individuals who can represent a collective patient voice for their patient community.

Selection criteria include the applicant's potential to meaningfully contribute to the activities of the PEC, ability to represent and express the patient voice for their 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 factors (such as age, gender, ethnicity, education level, income) and disease experience. PEC members are required to be residents of the United States and must be 18 years of age or older.

Financial and other conflicts of interest will not necessarily make applicants ineligible for membership in the PEC. However, applicants cannot be direct employees of the medical product development industry or a currently registered lobbyist for an FDA-regulated industry.

III. Responsibilities and Expectations

Participation as a PEC member is voluntary. Working meetings of the PEC will typically be held two to four times per year, either in person (in the Washington, DC area) or virtually (teleconference or webinar). Given the ongoing COVID–19 pandemic, meetings will be conducted virtually and may resume in-person when it is safe to do so. Additional meetings may be organized as needed, and currently include monthly, 1-hour teleconferences.

Reasonable accommodations will be made for members with special needs for travel or for participation in a meeting. Applications for PEC membership are encouraged from individuals of all ages, sexes, genders, sexual orientations, racial and ethnic groups, education levels, income levels, and those with and without disabilities. Travel support will be provided as applicable.

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

Additional responsibilities and expectations are set forth in the PEC Framework, which should be reviewed prior to submitting an application, and is available at *https://ctti-clinicaltrials.org/wp-content/uploads/2021/07/patient_engagement_collaborative_framework_-_revised_25jan2021.pdf.*

IV. Application Process

Any interested person may apply for membership on the PEC. To apply, go to *https://duke.qualtrics.com/jfe/form/SV_5nI1VVWVOaD59ky.* The application is completed online and includes questions to help determine eligibility for the PEC, demographic and other background questions, and four brief

essay questions. Many of the demographic questions are optional. The brief essay questions, to be answered in 500 characters or fewer (including spaces), are as follows:

- Please explain why you would have an outstanding ability to represent and express the patient voice for the disease area(s) you selected above.
- Please give a few examples of experiences that demonstrate your outstanding ability to work across or interact with stakeholders in the medical product development and regulatory processes.
- Please explain how you have established an understanding of the medical product development and regulatory processes.
- Please tell us why you are interested in becoming a member of the PEC and how you would be able to contribute.

Completing the application also involves submitting: (1) A current one-page résumé or bio that summarizes your patient advocacy experience and related activities (PDF format required) and (2) A one-page letter of endorsement from a patient group with which the applicant has worked closely on activities that are relevant to the PEC (PDF format required). Please note, only the application and the two documents specified above will be reviewed. Your completed application form, résumé or bio, and letter of endorsement should all be submitted at the same time.

The résumé or bio must provide examples and descriptions of relevant activities and experiences related to the applicant's qualifications for PEC membership. The letter of endorsement should emphasize information relevant to the criteria for membership described above. This letter must be from and written by someone other than yourself. The letter may address topics such as the applicant'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 processes, and other information that may be helpful in evaluating the applicant's qualifications as a potential member of the PEC.

Applications will be accepted until 11:59 p.m. eastern time on October 19, 2022 or until 75 applications are received, whichever happens first. Only complete applications will be considered.

The application review period will take a minimum of 2 months after 11:59 p.m. eastern time on October 19, 2022.

Additional information may be needed from some applicants during the review period, including information relevant to understanding potential sources of conflict of interest, in which case applicants will be contacted directly. All applicants (both those selected for PEC membership and those who are not selected) will be notified of the final application decision no later than the end of the 2022 calendar year.

Dated: September 12, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–20221 Filed 9–16–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2109]

Cardiovascular and Renal Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Cardiovascular and Renal Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held virtually on November 16, 2022, from 9:30 a.m. to 5 p.m. eastern time.

ADDRESSES: Please note that due to the impact of this COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2022–N–2109. The docket will close on November 15, 2022. Either electronic or written comments on this public meeting must be submitted by November 15, 2022. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. eastern time at the end of November 15, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Comments received on or before November 1, 2022, will be provided to the committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is canceled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments 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–2022–N–2109 for ''Cardiovascular and Renal Drugs Advisory Committee;