coaching funders or providers, ECE center directors, coaches, teachers, and FCC providers.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
State coaching informant interview protocol	45	23	1	1	23
ECE setting eligibility screener	173	87	1	0.25	22
Center director survey	60	30	1	0.5	15
Coach survey	90	45	1	0.5	23
Teacher/FCC provider survey	172	86	1	0.58	50
Center director semi-structured interview protocol	12	6	1	1.5	9
Coach semi-structured interview protocol	12	6	1	1	6
Teacher/FCC provider semi-structured interview protocol	12	6	1	1	6
Coach supervisor semi-structured interview protocol	12	6	1	0.5	3

Estimated Total Annual Burden Hours: 157.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Mary Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2017–27578 Filed 12–21–17; 8:45 am]

BILLING CODE 4184–22–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0307]

Amendment to ''Revised Preventive Measures To Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Products; Guidance for Industry;'' 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 ''Amendment to 'Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Products; Guidance for Industry;' Draft Guidance for Industry.'' The draft guidance document provides blood collection establishments with revised recommendations intended to reduce the possible risk of transmission of variant Creutzfeldt-Jakob Disease (vCJD) by blood and blood products by revising and removing certain recommended deferrals for geographic risk of bovine spongiform encephalopathy (BSE) exposure and recommending deferral for individuals with a history of blood transfusion in Ireland from 1980 to the present. The recommendations apply to the collection of Whole Blood and blood components intended for transfusion or for use in further manufacturing into injectable and non-injectable products, including recovered plasma, Source Leukocytes and Source Plasma.

The draft guidance, when finalized, will amend the document entitled ''Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Products; Guidance for Industry'' updated January 2016 (''2016 vCJD Guidance'') by incorporating into an updated final guidance any new recommendations adopted. All other recommendations in the 2016 vCJD Guidance will remain unchanged.

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 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–2012–D–0307 for ''Amendment to 'Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Products; Guidance for Industry;' Draft Guidance for Industry.'' 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 Fishers 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 the draft guidance 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 the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Melissa Segal, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Amendment to 'Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Products; Guidance for Industry;' Draft Guidance for Industry.'' The draft guidance provides blood collection establishments with revised recommendations intended to reduce the possible risk of transmission of vCJD by blood and blood products. The draft guidance, when finalized, will amend FDA's current recommendations by revising and removing certain recommended deferrals for geographic risk of BSE exposure; and recommending deferral for individuals with a history of blood transfusion in Ireland from 1980 to the present. The draft guidance also includes recommendations for blood collection establishments to update their donor history questionnaires (DHQ), including full-length and abbreviated DHQs and accompanying materials, and processes to incorporate the recommendations provided in the guidance, and recommendations for licensed establishments on how to report such changes to FDA. The recommendations apply to the collection of Whole Blood and blood components intended for transfusion or for use in further manufacturing into injectable and non-injectable products, including recovered plasma, Source Leukocytes and Source Plasma. While this draft guidance specifically provides revised recommendations to address vCJD risk, we may address Creutzfeldt-Jakob Disease (CJD) risk in future guidance documents.

The revised donor deferral recommendations are based on the results of an FDA quantitative risk assessment model. The model was developed to rank the risk of vCJD in different countries, to evaluate risk reduction and donor loss resulting from the current donor deferral policy compared with alternative policies, and to evaluate the potential additional reduction in risk afforded by leukocyte reduction of red blood cells. The model estimated that the United Kingdom, Ireland, and France, the three countries with the highest vCJD risks, contributed 95 percent of the total vCJD risk in the United States. The model also predicted that a revised policy of deferring donors only for time spent in these three countries would maintain a level of blood safety similar to that resulting from current policy, assuming approximately 71.3 to 95 percent of red blood cells currently transfused in the United States are leukocyte reduced. Based on its value in reducing the risk of transfusion-transmitted vCJD and its other medical benefits, FDA continues to consider potential rulemaking that would require leukocyte reduction of red blood cells and platelets intended for transfusion. The draft guidance, when finalized, will amend the 2016 vCJD Guidance.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Products.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and

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