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]

BILLING CODE 4164–01–P

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

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–1995–D–0288 (formerly Docket No. 95D–0052) for ''Chemistry, Manufacturing, and Controls Changes to an Approved Application: Biological Products.'' 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 *http://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: Jessica T. Walker, 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 ''Chemistry, Manufacturing, and Controls Changes to an Approved Application: Certain Biological Products; Draft Guidance for Industry.'' The draft guidance, when finalized, is intended to assist applicants and manufacturers of licensed biological products in determining which reporting category is appropriate for a change in CMC to an approved BLA as specified in 21 CFR 601.12. 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 under § 601.12.

FDA issued the July 1997 guidance (62 FR 39904; July 24, 1997) to assist applicants in determining which reporting mechanism is appropriate for reporting a change to an approved application to reduce the burden on manufacturers when reporting changes and to facilitate the approval process of the change being made. We are updating the July 1997 guidance to accommodate advances in manufacturing and testing technology and to clarify the FDA's current thinking on assessing reportable changes. The updated guidance applies to certain biological products licensed under the Public Health Service Act (PHS Act), including in vitro diagnostics licensed under BLAs. This draft guidance applies to all manufacturing locations, including contract locations. The following biological products are not within the scope of this guidance: Whole blood, blood components, source plasma, and source leukocytes. This draft guidance also does not apply to human cells, tissues, and cellular and tissue-based products regulated solely under section 361 of the PHS Act (42 U.S.C. 264), as described in 21 CFR part 1271; specified biotechnology and specified synthetic biological products; and biosimilar biological products subject to licensure under section 351(k) of the PHS Act. The draft guidance, when finalized, is intended to supersede the July 1997 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 ''Chemistry, Manufacturing, and Controls Changes to an Approved Application: Certain Biological 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 also 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 part 210 and

21 CFR part 211 have been approved under OMB control number 0910–0139; the collections of information in 21 CFR 601.12 have been approved under OMB control numbers 0910–0338, and the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073.

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 19, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–27589 Filed 12–21–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–new]

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 January 22, 2018.

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: I Can Do It, You Can Do It! Program Evaluation.

Type of Collection: New.

OMB No. 0990—NEW—Office within OS—President's Council on Fitness, Sports & Nutrition (PCFSN), Office of the Assistant Secretary for Health.

Abstract: Approximately 56 million children and adults living in the United States have some level of disability. Despite physical activity and good nutrition being the cornerstones of evidence-based health promotion interventions for reducing the risk of comorbidities (*e.g.,* diabetes, heart disease, and stroke), many people with a disability or caregivers who have a child with a disability experience substantial difficulty accessing these programs. Benefits of physical activity and good nutrition have been well documented for individuals with and without a disability, including: reducing the risk of developing chronic diseases and medical conditions. Studies also show that one-on-one mentoring through healthy eating, physical activity, and sport participation can support the development of social skills, improve positive self-esteem, and increase self-confidence among children and adults with a disability. I Can Do It, You Can Do It! partners with K–12 schools and school districts, colleges and universities, and other community-based entities to provide access and opportunities for children and adults with a wide range of physical and cognitive disabilities to lead healthy, active lives. PCFSN plans to conduct a rigorous evaluation of I Can Do It, You Can Do It! The evaluation will assess the impact of the program on mentee level outcomes (impact evaluation) as well as barriers and facilitators to program implementation (process evaluation). Evaluation activities will take place in 10 sites between summer 2018 and fall 2019. The I Can Do It, You Can Do It! sites recruited to participate in the evaluation will be identified from a list of schools and community organizations that have signed up to be program sites. The aims of the process evaluation are to determine what parts of the program were successful, the usefulness of program materials, and what changes are necessary to improve the administration of the program. The aims of the impact evaluation are to examine how ICDI impacts Mentee physical activity and healthy eating behaviors. The information collected for the I Can Do It, You Can Do It! Program Evaluation will allow the OPCFSN and partners to assess the impact of the program and gather critical information for improvement. OMB approval is requested for three years. Participation in I Can Do It, You Can Do It! is voluntary and there are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN TABLE

Forms	Respondents	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
Site Application	Site Coordinator	10	1	7/60	1
Partner Application	National Partner Organizations	50	1	15/60	12
Site Annual Follow-Up Survey	Site Coordinator	10	1	5/60	1
End of Wave 1 Interview	Site Coordinator	10	1	30/60	5
End of Wave 1 Feedback Survey	Site Coordinator	10	1	11/60	2
End of Wave 2 Interview	Site Coordinator	10	1	30/60	5
End of Wave 2 Feedback Survey	Site Coordinator	10	1	6/60	1
Technical Assistance Assessment	Site Coordinator	10	1	10/60	2
Mentee Pre-Assessment	Mentee/Program Participant	700	1	20/60	233
Mentee Post-Assessment	Mentee/Program Participant	700	1	25/60	292
Mentor Feedback Survey	Mentor	700	1	8/60	94
Weekly Goal-Setting Guide	Mentor	700	8	10/60	936
Total			19		1,584