the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the 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 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Tami Belouin, 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 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.'' The guidance document provides blood collecting establishments and manufacturers of plasma derivatives with comprehensive recommendations intended to minimize the possible risk of transmission of CJD and vCJD from blood and blood products. The guidance is the latest in a series of guidances addressing the risk of CJD and vCJD transmission by blood and blood products.

The guidance amends the 2010 guidance (May 27, 2010; 75 FR 29768) and finalizes the 2012 draft guidance (June 11, 2012; 77 FR 34390) by providing revised labeling recommendations for plasma-derived products, including albumin and products containing plasma-derived albumin. The guidance also provides manufacturers of plasma-derived products with recommendations on how to report the labeling changes to FDA under 21 CFR 601.12. Additional changes to the guidance include adding information in the background section relevant to the new labeling recommendations; providing updated information on the global vCJD and Bovine Spongiform Encephalopathy epidemics; clarifying the reentry criteria for a donor with a family history of CJD; clarifying the requirements related to biological product deviation reporting; and, updating, adding, and removing certain footnotes and references. FDA received four comments on the 2012 draft guidance, and those comments were considered in the finalization of the draft guidance.

This guidance does not address potential changes to the geographic exposure based deferrals for risk of vCJD. FDA discussed such potential changes with its Transmissible Spongiform Encephalopathies Advisory Committee in June 2015 and intends to address revised recommendations for geographic donor deferrals in future guidance documents.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents 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; Guidance for Industry. 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.

II. Paperwork Reduction Act of 1995

This 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 have been approved under OMB control number 0910–0338; the collections of information in 21 CFR 606.100 have been approved under OMB control number 0910–0116; and the collections of information in 21 CFR 600.14 and 606.171 have been approved under OMB control number 0910–0458.

III. Electronic Access

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

Dated: January 7, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–00536 Filed 1–13–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Self-Affirmation Construct Validity (NCI)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) The quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

To Submit Comments and for Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact*: Rebecca Ferrer, Program Director, Basic Biobehavioral and Psychological Sciences Branch, Behavioral Research Program, Division of Cancer Control and Population Sciences, National Cancer Institute, 9609 Medical Center Dr., Rockville MD 20852. or call non-toll-free number (240) 276–6914 or Email your request, including your address to: *ferrerra@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Proposed Collection: Self-affirmation Construct Validity, 0925–NEW, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: This information collection, seeks to refine a theory about how self-competence and values play a role in defensive responses to health communications. Although theoretically-driven research has shown that self-affirmation—a process by which individuals reflect on values that are important to them—can improve responses to health and cancer communications, the ''active ingredient'' (or mechanisms underlying effectiveness) of self-affirmations is unknown. Self-affirmation is a potent means of augmenting the effectiveness of threatening health communications. Individuals tend to be defensive against information suggesting their behavior puts them at risk for disease or negative health. Previous evidence suggests that self-affirmation may reduce defensiveness to threatening health information, increasing openness to the message and resulting in increased disease risk perceptions, disease-related worry, intentions to engage in preventive behavior, and actual behavioral change. Understanding the mechanisms that explain these robust effects would yield evidence important for dissemination, including ways to refine self-affirmation interventions and make them more potent, which could change the ways that public health messages are constructed. This research can inform NCI scientific priorities and investments in self-affirmation research. The results of the information collection will be used to further develop and improve self-affirmation theory. These findings may allow future researchers to develop and test cancer prevention interventions.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 717.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Types of respondents	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total hour burden
Screener	General Public	10,000	1	1/60	167
Study	General Public	1,100	1	30/60	550

Dated: January 7, 2016.

Karla Bailey,

Project Clearance Liaison, National Cancer Institute, NIH.

[FR Doc. 2016–00545 Filed 1–13–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–0085]

Agency Information Collection Activities: Administrative Rulings

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security

ACTION: 60-Day notice and request for comments; extension of an existing collection of information.

SUMMARY: U.S. Customs and Border Protection (CBP) of the Department of Homeland Security will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: Administrative Rulings. CBP is proposing that this information collection be extended with a change to the burden hours but no change to the information required. This document is published to obtain comments from the public and affected agencies.

DATES: Written comments should be received on or before March 14, 2016 to be assured of consideration.

ADDRESSES: Written comments may be mailed to U.S. Customs and Border Protection, Attn: Tracey Denning, Regulations and Rulings, Office of International Trade, 90 K Street NE., 10th Floor, Washington, DC 20229–1177.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Tracey Denning, U.S. Customs and Border Protection, Regulations and Rulings, Office of International Trade, 90 K Street NE., 10th Floor, Washington, DC 20229–1177, at 202–325–0265.

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13). The comments should address: (a) Whether the 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 estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology; and (e) the annual cost burden to respondents or record keepers from the collection of information (total capital/startup costs and operations and maintenance costs). The comments that are submitted will be summarized and included in the CBP request for OMB approval. All comments will become a matter of public record. In this document, CBP is soliciting comments concerning the following information collection:

Title: Administrative Rulings.

OMB Number: 1651–0085.

Abstract: The collection of information in 19 CFR part 177 is necessary in order to enable Customs and Border Protection (CBP) to respond to requests by importers and other interested persons for the issuance of administrative rulings. These rulings pertain to the interpretation of applicable laws related to prospective and current transactions involving classification, marking, and country of origin. The collection of information in Part 177 of the CBP Regulations is also necessary to enable CBP to make proper decisions regarding the issuance of binding rulings that modify or revoke prior CBP binding rulings. This collection of information is authorized by 19 U.S.C. 66, 1202, (General Note 3(i), Harmonized Tariff Schedule of the United States). The application to obtain an administrative ruling is accessible at: *https://apps.cbp.gov/erulings.*

Action: CBP proposes to extend the expiration date of this information