with trading partners to ensure that all the proper product tracing information is provided and captured. To minimize possible disruptions in the distribution of prescription drugs in the United States, FDA does not intend to take action against trading partners who do not, prior to May 1, 2015, provide or capture the product tracing information required by section 582(b)(1), (c)(1), and (e)(1) of the FD&C Act. This compliance policy is limited to the requirements that trading partners provide and capture product tracing information; it does not extend to other requirements in section 582 of the FD&C Act, such as verification of suspect and illegitimate products (including quarantine, investigation, notification, and recordkeeping) or the requirement to engage only in transactions with authorized trading partners.

II. Comments

This guidance is for immediate implementation. FDA is issuing this guidance for immediate implementation in accordance with § 10.115(g)(2). Submit one set of either electronic or written comments on this guidance at any time. Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. You should identify all comments with Docket No. FDA–2014–D–2254.

III. Electronic Access

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

Dated: December 23, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–30608 Filed 12–30–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery (NIDA).

SUMMARY: National Institute on Drug Abuse (NIDA), National Institutes of Health, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public to take this opportunity to comment on the ''Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery '' for approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 et. seq.). This collection was developed as part of a Federal Government-wide effort to streamline the process for seeking feedback from the public on service delivery. This notice announces our intent to submit this collection to OMB for approval and solicits comments on specific aspects for the proposed information collection.

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: Genevieve deAlmeida, Ph.D., Health Research Evaluator, Office of Science Policy and Communications, National Institute on Drug Abuse, NIH, 6001 Executive Boulevard, Bethesda, MD, Bethesda, MD 20892–9557, or call non-toll-free number (301) 594–6802, or Email your request, including your address to: *dealmeig@nida.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: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery (NIDA), 0925–0655, Expiration Date 3/31/2015, EXTENSION, National Institute on Drug Abuse (NIDA).

Need and Use of Information Collection: The information collected under this clearance will be qualitative customer and stakeholder feedback information—their perceptions, experiences and expectations of services, issues with service, to focus attention on areas where communication, training or changes in operations might improve delivery of products or services. The information will be useful and will allow for collaborative and actionable communications between the Agency and its customers and stakeholders, and will contribute directly to improving the programs and management of them.

The information will not yield data that can be generalized to the overall population. The information may also be formative for the purpose of developing a concept for a new service program or dissemination program. The collections may still be eligible for submission for other generic mechanisms designed to yield quantitative results.

The primary objectives are to obtain feedback on programs from customers and stakeholders, that would help make positive changes to the programs, or to assist in developing a new program or dissemination initiative, or to test medical tools and devices for usability, feasibility, and pilot testing of survey questionnaires for understandability. Data collection methods to be used in these studies include web-based and mailed surveys, focus groups, interviews with small groups, ad hoc collections at Conferences. The findings will provide valuable information to assist in improving programs that serve the public, and in developing good tools and devices to serve the public. OMB approval is requested for 3 years.

NIDA will only submit a collection for approval under this generic clearance if it meets the following conditions:

- The collections are voluntary;
- The collections are low-burden for respondents (based on considerations of total burden hours, total number of respondents, or burden-hours per respondent) and are low-cost for both the respondents and the Federal Government;
- The collections are non-controversial and do not raise issues of concern to other Federal agencies;
- Any collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future;
- Personally identifiable information (PII) is collected only to the extent necessary and is not retained;
- Information gathered will be used only internally for general service improvement and program management purposes and is not intended for release outside of the agency;
- Information gathered will not be used for the purpose of substantially informing influential policy decisions; and
- Information gathered will yield qualitative information; the collections will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the population of study.

Feedback collected under this generic clearance provides useful information, but it does not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses

require more rigorous designs that address: The target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior to fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

As a general matter, information collections will not result in any new system of records containing privacy information and will not ask questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments are invited on: (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 estimate 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 of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget control number.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 1,312.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of collection	Number of respondents	Annual frequency per response	Hours per response	Total hours
Customer outcomes and usability testing	888	1	40/60	592
Customer Satisfaction and needs assessment survey	600	1	40/60	400
Focus Groups	60	1	1	60
Small Discussion Groups	60	1	1	60
Pilot Testing of instruments for applicability among diverse populations	300	1	40/60	200
Total				1,312

Dated: December 24, 2014.

Genevieve deAlmeida,

Project Clearance Liaison, NIDA, NIH.

[FR Doc. 2014–30656 Filed 12–30–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60 Day Comment Request Prevalence, Incidence, Epidemiology and Molecular Variants of HIV in Blood Donors in Brazil (NHLBI)

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 Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH), will publish periodic summaries of proposed projects 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 on 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) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to 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: Simone Glynn, MD, Project Officer/ICD Contact, Two Rockledge Center, Suite 9142, 6701 Rockledge Drive, Bethesda, MD 20892, or call non-toll-free number (301)–435–0065, or Email your request to: *glynnsa@nhlbi.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Comments 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: Prevalence, Incidence, Epidemiology and Molecular Variants of HIV in Blood Donors in Brazil 0925–0597 expiration date, July 31, 2015, Extension, National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH).

Need and Use of Information Collection: Establishing and monitoring viral prevalence and incidence rates, and identifying behavioral risk behaviors for HIV infection among