that facility's healthcare system. Are these factors appropriate and/or sufficient to both mitigate risks and to provide patient access if warranted? Should FDA use different factors to best balance patient safety and patient access?
- For the categories of Traditional LDTs and LDTs for Unmet Needs, one of the factors for enforcement discretion is whether the LDT is both manufactured and used by a healthcare facility laboratory (such as one located in a hospital or clinic) for a patient that is being diagnosed and/or treated at that same healthcare facility, or within the facility's healthcare system. To further clarify this factor, the Framework draft guidance document explains that ''healthcare system'' refers to a collection of hospitals that are owned and operated by the same entity and that share access to patient care information for their patients, such as, but not limited to, drug order information, treatment and diagnosis information, and patient outcomes. If this is an appropriate factor to use, are the considerations about which types of facilities would or would not be included within a healthcare system as defined by the draft guidance appropriate? Is there an alternative definition of healthcare system that would be more appropriate?
- Do the FDA-proposed categories for continued enforcement discretion appropriately encompass the LDTs that should remain under enforcement discretion? Should the scope of proposed categories be broadened or narrowed? If so, how? Should additional categories for continued enforcement discretion be added or proposed categories removed? If so, which categories? For any new proposed categories, what are the appropriate factors in considering enforcement discretion?
- Is the information provided detailed enough for laboratories to make a determination that their LDT falls within one of these categories of continued enforcement discretion?

Session 4: Notification and Adverse Event Reporting (MDRs)
- Will notification be adequate to provide FDA, laboratories, providers, patients, and other members of the public a comprehensive list of what tests are currently available for a specific intended use?
- Would it be sufficient to allow laboratory networks (*i.e.,* more than one laboratory under the control of the same parent entity) that offer the same test in multiple laboratories throughout their network to submit a single notification for that test?
- Are there certain types of LDTs for which the Agency should neither enforce requirements for registration and listing nor request notification in lieu of registration and listing?
- How can FDA leverage other information in the community to reduce the information collection associated with notification for laboratories while still obtaining sufficient information to inform the LDT classification and prioritization process?

Session 5: Public Process for Classification and Prioritization
- How should FDA structure the advisory panels that will be convened to provide input to help FDA classify LDTs and prioritize them for enforcement of FDA premarket review requirements?
- Which stakeholders should be able to present relevant information or views at the panel meetings to discuss the classification and prioritization of LDTs?
- What factors should be considered in determining LDT classification and risk?
- How should the advisory panel process weigh these factors when providing input for classifying LDTs and prioritizing LDTs for enforcement of FDA premarket review requirements?

Session 6: Quality System Regulation
- How can laboratories best leverage their current processes and procedures, implemented to meet CLIA accreditation requirements, to meet the FDA QS regulation requirements in the least burdensome manner?
- Are there FDA QS requirements that differ from CLIA requirements that FDA should continue not to enforce for laboratories that make LDTs?
- What additional resources will laboratories need in order to assist them with implementation of the QS regulation?
- What is the appropriate timeframe for phase-in enforcement of QS regulation requirements in general and for design controls specifically?

Dated: November 17, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–27713 Filed 11–21–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1818]

New Clinical Trials Demographic Data; Availability for Comment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for public comment of Demographic Subgroup Data for FDA Approved Products on FDA's Internet Web site. This new posting implements Action 3.1 from Priority 3 of the Food and Drug Administration Safety and Innovation Act (FDASIA) Section 907 Action Plan designed to improve the availability and transparency of clinical trial demographic subgroup data. FDA is requesting comments on the format, content, and overall usability of the site to determine whether this approach is user friendly to the public.

DATES: Submit electronic or written comments on the content by January 23, 2015.

ADDRESSES: Submit electronic comments on the Web page 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.

FOR FURTHER INFORMATION CONTACT: Laurie Haughey, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 240–402–6511, *Laurie.Haughey@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of clinical trial demographic data for consumers on FDA's Internet Web site at *www.fda.gov/drugtrialssnapshot.*

On July 9, 2012, the President signed FDASIA (Pub. L. 112–144) into law. Section 907 of FDASIA requires that FDA report on and address certain information regarding clinical trial participation by demographic subgroups and subset analysis of the resulting data. Specifically, section 907(a) of FDASIA requires the Secretary of Health and Human Services (the Secretary), acting through the FDA Commissioner, to publish on FDA's Internet Web site a report ''addressing the extent to which clinical trial participation and the inclusion of safety and effectiveness

data by demographic subgroups including sex, age, race, and ethnicity, is included in applications submitted to the FDA,'' and provide such publication to Congress. The report, entitled ''Reporting of Inclusion of Demographic Subgroups in Clinical Trials and Data Analysis in Applications for Drugs, Biologics, and Devices,'' was posted on FDA's Internet Web site in August 2013 and is available at *http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/ucm356316.htm.*

Section 907(b) of FDASIA further requires the Secretary, again acting through the Commissioner, to publish an action plan on FDA's Internet Web site and provide such publication to Congress. The action plan is to contain recommendations, as appropriate, to improve the completeness and quality of analyses of data on demographic subgroups in summaries of product safety and effectiveness and in labeling; on the inclusion of such data, or the lack of availability of such data in labeling; and on ways to improve public availability of such data to patients, health care providers, and researchers. These recommendations are to include, as appropriate, a determination that distinguishes between product types and applicability. The action plan is due not later than 1 year after the publication of the report described previously. The action plan entitled ''FDA Action Plan to Enhance the Collection and Availability of Demographic Subgroup Data'' was published in August 2014 and is available at *http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/ucm356316.htm.*

Priority three of the action plan aims to make demographic data more available and transparent by, amongst other things, posting demographic composition and analysis by subgroup in pivotal clinical studies for FDA-approved medical products. The first iteration of FDA's publication of this data is available at *www.fda.gov/drugtrialssnapshot.*

II. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

III. Electronic Access

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

Dated: November 19, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–27732 Filed 11–21–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Assessing an Online Process To Study the Prevalence of Drugged Driving in the U.S.: Development of the Drugged Driving Reporting System

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 Institute on Drug Abuse (NIDA), 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 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 request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Harold Perl, Ph.D., Chief, Prevention Research Branch, Division of Epidemiology, Services & Prevention Research, NIDA, 6001 Executive Blvd., Rockville, MD 20852 or call this non-toll-free number (301) 443–6504, or email your request, including your address to: *hperl@nida.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: Assessing an Online Process to Study the Prevalence of Drugged Driving in the U.S: Development of the Drugged Driving Reporting System. Type of Information Collection Request: 0925–NEW. National Institute on Drug Abuse (NIDA), National Institutes of Health (NIH).

Need and Use of Information Collection: The study seeks to provide an improved understanding of the prevalence of drugged driving among adult drivers in the U.S and will assess the effectiveness of the online survey implementation process. The primary objectives of the study are to: (a) To provide comprehensive data on drugged driving; (b) determine if the Drugged Driving Survey Instrument (DDS) is an effective and accurate measure of drugged driving among licensed U.S. Drivers aged 18 and older; and, (c) to assess the effectiveness of the survey implementation process, including various levels of incentives for participation to determine the appropriate/optimal incentive amount needed to obtain the desired number of total survey respondents within the timeframe within which survey data will be collected. The findings will provide valuable information concerning various aspects of substance use and driving behavior, including: (1) Demographic information about drivers who do and do not drive while impaired by medication and/or drugs (*e.g.* age, zip code, type of driver's license); (2) which drugs/medications are most likely to be used while driving; (3) drivers' beliefs and attitudes toward drugged driving. OMB approval is requested for 2 years. There are no direct costs to respondents other than their time. The total annualized estimated burden hours are 750.