compound human drugs called ''outsourcing facilities.'' Section 503B(d)(4) of the FD&C Act (21 U.S.C. 353B(d)(4)) defines an outsourcing facility, in part, as a facility that complies with all of the requirements of section 503B, including registering with FDA as an outsourcing facility and paying associated fees. If the conditions outlined in section 503B(a) of the FD&C Act are satisfied, a drug compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility is exempt from certain sections of the FD&C Act, including section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use) and section 505 (21 U.S.C. 355) (concerning the approval of human drug products under new drug applications (NDAs) or abbreviated new drug applications (ANDAs)). Drugs compounded in outsourcing facilities are not exempt from the requirements of section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice for drugs). This guidance is intended to assist compounding facilities that wish to register as outsourcing facilities to register with FDA and discusses the process for registering, re-registering, and de-registering.

In the **Federal Register** of December 4, 2013 (78 FR 72899), FDA issued a notice announcing the availability of the draft version of this guidance. That draft guidance set forth an interim and electronic submission method for human drug compounders that elect to register as outsourcing facilities. The comment period on the draft guidance ended on February 3, 2014. FDA received nine comments on the draft guidance. Some of the received comments raised issues that were not directly pertinent to the topics addressed in this guidance. FDA intends to consider those comments as they relate to issues being addressed in other policy documents being developed by the Agency.

In response to received comments or on its own initiative, FDA made the following changes as it finalized this guidance: (1) We included a phone number for a point of contact; (2) we deleted reference to an alternative interim registration method; (3) we added information on how a registered outsourcing facility can de-register; (4) we clarified what registration information will be made public; (5) we clarified the standard to be used to grant a waiver of the electronic submission requirements; and (6) we made grammatical and other minor editorial changes to improve clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act

This guidance contains collections of information that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information have been approved under OMB control number 0910–0777.

III. Comments

Interested persons can 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 can 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.*

IV. 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 18, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–27693 Filed 11–21–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2011–D–0360 and FDA–2011–D–0357]

Framework for Regulatory Oversight of Laboratory Developed Tests; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs).'' The purpose of this workshop is to discuss FDA's proposal for a risk-based framework for addressing the regulatory oversight of a subset of *in vitro* diagnostic devices (IVDs) referred to as laboratory developed tests (LDTs), which are intended for clinical use and designed, manufactured and used within a single laboratory, and provide an additional opportunity for public comment

Dates and Times: The 2-day public workshop will be held on January 8, 2015, from 8:30 a.m. to 5:30 p.m. and on January 9, 2015 from 8:30 a.m. to 5:30 p.m.

Location: The public workshop will be held at the Natcher Center at the National Institutes of Health Campus, 9000 Rockville Pike, Bldg. 45, Auditorium, Bethesda, MD 20814. For parking and security information, please refer to *http://www.nih.gov/about/visitor/.*

Contact Person: Allen Webb, Center for Devices and Radiological Health, Food and Drug Administration, Bldg. 66, Rm 5675, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240–402–4217, *LDTframework@fda.hhs.gov.*

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by December 12, 2014, at 4 p.m. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration on the day of the public workshop will be provided beginning at 8 a.m.

If you need special accommodations due to a disability, please contact Susan Monahan, (email: *Susan.Monahan@fda.hhs.gov* or phone: 301–796–5661) no later than December 19, 2014.

To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this meeting/public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, email, and telephone number. If you are unable to register online, please contact Susan Monahan (see *Registration.*) Registrants will receive confirmation after they have been accepted and will be notified if they are on a waiting list.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. Persons interested in viewing the Webcast must register online. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements and connection access information after registration and prior to the meeting. If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *http://www.adobe.com/go/connectpro_overview.* (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.) The Webcast will be recorded and posted on FDA's Web site after the meeting.

Requests for Oral Presentations: This public workshop includes topic-focused public comment sessions. During online registration you may indicate if you wish to present during a public comment session, and which topics you wish to address. FDA has included general topics in this document. FDA will do its best to accommodate requests to make public comment. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. Following the close of registration, FDA will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by December 17, 2014. All requests to make oral presentations must be received by the close of registration on December 12, 2014. If selected for presentation, any presentation materials must be emailed to Allen Webb (see *Contact Person*) no later than January 6, 2015. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Comments: In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop topics. The deadline for submitting comments related to this public workshop is February 2, 2015.

Regardless of attendance at the public workshop, interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. 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. In addition, when responding to specific questions as outlined in section II of this document, please identify the question you are addressing. 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.*

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcripts will also be available approximately 45 days after the public workshop on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list).

SUPPLEMENTARY INFORMATION:

I. Background

In 1976, Congress enacted the Medical Device Amendments (MDA), which amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to create a comprehensive system for the regulation of medical devices intended for use in humans. At that time, the definition of a device was amended to make explicit that it encompassed in vitro diagnostic devices (IVDs): ''The term 'device'. . .means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article. . . .'' (section 201(h) of the FD&C Act (21 U.S.C. 321(h)). The definition of device applies equally to IVDs manufactured by conventional device manufacturers and those manufactured by laboratories. An IVD, therefore, meets the device definition irrespective of where and by whom it is manufactured.

Since the implementation of the MDA of 1976, FDA has exercised enforcement discretion so that the Agency has generally not enforced applicable provisions under the FD&C Act and FDA regulations with respect to LDTs, a subset of IVDs that are intended for clinical use and designed, manufactured, and used within a single laboratory.

In 1976, LDTs were mostly manufactured in small volumes by local laboratories. Many laboratories manufactured LDTs that were similar to well-characterized, standard diagnostic devices, as well as other LDTs that were intended for use in diagnosing rare diseases or for other uses to meet the needs of a local patient population. LDTs at the time tended to rely on the manual techniques used by laboratory personnel. LDTs were typically used and interpreted directly by physicians and pathologists working within a single institution that was responsible for the patient. In addition, historically, LDTs were manufactured using components that were legally marketed for clinical use (*i.e.,* general purpose reagents, immunohistochemical stains, and other components marketed in compliance with FDA regulatory requirements).

Although some laboratories today still manufacture LDTs in this ''traditional'' manner, the landscape for laboratory testing in general, and LDTs along with it, has changed dramatically since 1976. Today, LDTs are often used in laboratories that are independent of the healthcare delivery entity. Additionally, LDTs are frequently manufactured with components and instruments that are not legally marketed for clinical use and also rely more heavily on complex, high-tech instrumentation and software to generate results and clinical interpretations. Moreover, technological advances have increased the use of diagnostic devices in guiding critical clinical management decisions for high-risk diseases and conditions, particularly in the context of personalized medicine.

Business models for laboratories have also changed since 1976. With the advent of overnight shipping and electronic delivery of information (*e.g.,* device results), a single laboratory can now easily provide device results nationally and internationally. Today, many new LDT manufacturers are large corporations that nationally market a limited number of complex, high-risk devices, in contrast to 1976 when hospital or public health laboratories used a wide range of devices that were generally either well characterized and similar to standard devices; used to diagnose rare diseases; or designed specifically to meet the needs of their local patients. Together, these changes

have resulted in a significant shift in the types of LDTs developed, the business model for developing them, and the potential risks they pose to patients.

Because of changes in the complexity and use of LDTs and the associated increased risks, as described earlier, FDA believes the policy of general enforcement discretion towards LDTs is no longer appropriate. To initiate this step toward greater oversight, FDA held a 2-day public meeting on July 19 and 20, 2010, to provide a forum for stakeholders to discuss issues and concerns surrounding greater oversight of LDTs. Comments submitted to the public docket for the July 19 and 20, 2010, public meeting were reviewed and, as appropriate, incorporated into FDA's current proposed framework for regulatory oversight of LDTs. FDA's July 31, 2014, Notification to Congress concerning the Agency's intent to issue the draft guidance, ''Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)'' (Framework draft guidance document), and the accompanying draft guidance, ''FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs),'' was made publicly available, and these draft guidance documents were subsequently issued on October 3, 2014. See 79 FR 59776 and 79 FR 59779 (October 3, 2014). These documents describe a risk-based framework for addressing the regulatory oversight of LDTs, including FDA's priorities for enforcing premarket and postmarket requirements for LDTs as well as the process by which FDA intends to phase in enforcement of FDA regulatory requirements for LDTs over time. As outlined in the Framework draft guidance document, FDA proposes to continue to exercise enforcement discretion for all applicable regulatory requirements for LDTs used solely for forensic (law enforcement) purposes as well as certain LDTs for transplantation when used in certified, high-complexity histocompatibility laboratories. Additionally, FDA proposes to exercise enforcement discretion for applicable premarket review requirements and quality systems (QS) requirements, but enforce other applicable regulatory requirements, including registration and listing (with the option to provide notification instead) and adverse event reporting, for low-risk LDTs (class I devices), LDTs for rare diseases, Traditional LDTs and LDTs for Unmet Needs, as described in the Framework draft guidance document. For other high- and moderate-risk LDTs, FDA proposes to enforce applicable regulatory requirements, including registration and listing (with the option to provide notification instead) and adverse event reporting, and phase in enforcement of premarket and QS requirements in a risk-based manner.

With the publication of the draft guidances, FDA announced a public comment period soliciting feedback on all aspects of the guidance documents as well as on the following specific issues: (1) Factors for ''Traditional LDT'' and appropriate level of enforcement discretion for such tests; (2) factors for considering LDTs for rare diseases; (3) manufacture and use of LDTs solely within a healthcare system as a risk mitigation supporting some continued enforcement discretion; (4) timeframe for phase-in enforcement of QS regulation requirements for those LDTs called in for enforcement of premarket review requirements early in the implementation period; and (5) the appropriateness of a single notification for the same LDT manufactured by multiple labs owned by a single entity.

FDA intends to use this public workshop as a forum for open discussion with all stakeholders regarding these specific issues as well as other considerations for how to best balance patient safety and patient access in developing the finalized framework in a manner that best serves public health.

II. Topics for Discussion at the Public Workshop

Issues to be considered during the sessions include:

Session 1: Components of a Test and LDT Labeling Considerations

- What components do FDA cleared/approved tests and LDTs typically include?
- What labeling considerations should be taken into account for LDTs?
- How does LDT labeling affect and not affect physician consultation with the laboratory?

Session 2: Clinical Validity/Intended Use

- What is clinical validity and how is it demonstrated for IVDs, including LDTs?
- How are clinical claims or intended use related to clinical validity?
- What types of modifications may affect the intended use or significantly affect the performance of a test?

Session 3: Categories for Continued Enforcement Discretion

- As a factor for consideration of continued enforcement discretion for premarket review and QS regulation requirements for LDTs for rare diseases, the proposed framework for LDTs relies on the definition of a humanitarian use device (HUD) in 21 CFR 814.102(a)(5). Under this definition, an IVD may qualify for HUD designation when the number of persons in the United States who may be tested with the device is fewer than 4,000 per year. Is this an appropriate factor for LDTs for rare diseases? If not, what factor should FDA consider for LDTs for rare diseases?
- Should enforcement discretion be limited to tests for rare diseases that meet the definition of an LDT (a test designed, manufactured and used within a single laboratory)?
- Are the following three factors the appropriate controls to mitigate risks due to Traditional LDTs so that continued enforcement discretion is appropriate with respect to premarket review and quality system requirements whether the test is: (1) An LDT (designed, manufactured and used within a single laboratory); (2) comprised of only components and instruments that are legally marketed for clinical use, which have a number of regulatory controls in place, including reporting of adverse events; and (3) interpreted by laboratory professionals who are appropriately qualified and trained as required by the CLIA (Clinical Laboratory Improvement Amendments) regulations (see, *e.g.,* 42 CFR 493.1449), without the use of automated instrumentation or software for interpretation? Are these three factors also sufficient to support continued enforcement discretion in full (*i.e.,* for all regulatory requirements rather than just for premarket review and quality system requirements) for this category of LDTs? Should FDA instead consider different factors?
- FDA has proposed the following three factors for consideration of continued enforcement discretion for premarket review and QS requirements for LDTs for Unmet Needs whether: (1) The device meets the definition of an LDT (a test designed, manufactured and used by a single laboratory); (2) there is no FDA cleared or approved IVD available for that specific intended use; and (3) 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

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