biological products, medical devices, and combinations thereof.

To enhance human subject protection and reduce regulatory burden, the Department of Health and Human Services Office for Human Research Protections (OHRP) and FDA have been actively working to harmonize the agencies' regulatory requirements and guidance for human subject research, and the FDA draft guidance document was developed as a part of these efforts. Although the document is issued by FDA and is drafted as guidance that would apply to FDA-regulated clinical investigations, OHRP is considering whether to adopt the positions and recommendations proposed in this guidance for research regulated under the HHS protection of human subjects regulations, 45 CFR part 46, and to issue a joint OHRP and FDA guidance document on this topic when the final guidance document is developed. OHRP asks for public comment about whether a joint guidance document would be useful for the regulated community. In particular, OHRP is interested in public comment regarding whether FDA's draft guidance would be appropriate for all research regulated under 45 CFR part 46, including research studies other than clinical investigations or clinical trials, such as social and behavioral research studies. If different guidance should apply to social and behavioral research, or other non-FDA-regulated studies, OHRP asks that the public comments address how the guidance should differ from the proposed guidance for FDA-regulated clinical investigations.

OHRP specifically welcomes feedback regarding when it might or might not be appropriate, for studies other than clinical trials, for OHRP to recommend that researchers verify that the person signing the informed consent form is the subject participating in the research.

OHRP and FDA will consider these comments in deciding whether to issue a joint OHRP/FDA guidance document on this topic when the final guidance document is developed.

DATES: May 7, 2015.

ADDRESSES: You may submit comments identified by docket ID number HHS–OPHS–2015–0002 by one of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Enter the above docket ID number in the Enter Keyword or ID field and click on ''Search.'' On the next page, click the ''Submit a Comment'' action and follow the instructions.

Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions] to: Irene Stith-Coleman, Ph.D., Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852.

Comments received, including any personal information, will be posted without change to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Irene Stith-Coleman, Office for Human Research Protections, Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852; phone 240–453–6900; email *Irene.Stith-Coleman@hhs.gov.*

Dated: March 3, 2015.

Jerry Menikoff,

Director, Office for Human Research Protections.

[FR Doc. 2015–05301 Filed 3–6–15; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Human Genome Research Institute Special Emphasis Panel Loan Repayment Program.

Date: April 30, 2015.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Human Genome Research Institute, 3rd Floor Conference Room, 5635 Fishers Lane, Rockville, MD, (Telephone Conference Call).

Contact Person: Keith McKenney, Ph.D., Scientific Review Officer, National Human Genome Research Institute, 5635 Fishers Lane, Suite 4076, Bethesda, MD 20814, 301–594–4280, *mckenneyk@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: March 3, 2015.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–05305 Filed 3–6–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0647]

Complexities in Personalized Medicine: Harmonizing Companion Diagnostics Across a Class of Targeted Therapies; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA), in co-sponsorship with the American Association for Cancer Research (AACR) and the American Society of Clinical Oncology (ASCO), is announcing a public workshop entitled ''Complexities in Personalized Medicine: Harmonizing Companion Diagnostics Across a Class of Targeted Therapies.'' The objective of the workshop is to facilitate an in-depth discussion of harmonization of companion diagnostic devices across a class of targeted therapies. The workshop aims to foster collaborations in the clinical cancer research community; provide a deeper understanding of anticancer drug and device development related to personalized medicine; provide a unique perspective of personalized medicine; and help incorporate emerging scientific findings to harmonize companion diagnostics across a class of targeted therapies.

Date and Time: The public workshop will be held on March 24, 2015, from 8:30 a.m. to 4:30 p.m.

Location: The public workshop will be held at the Mayflower Hotel, Grand Ballroom, 1127 Connecticut Ave. NW., Washington, DC 20036, 202–347–3000.

Contact Persons: Kaitlyn Antonelli, American Society of Clinical Oncology, 2318 Mill Rd., suite 800, Alexandria, VA 22314, 571–483–1606, *Kaitlyn.Antonelli@asco.org*; Pamela Bradley, Center for Devices and Radiological Health, Office of In Vitro Diagnostics and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 240–731–3734, *Pamela.Bradley@fda.hhs.gov*; and Rasika Kalamegham, American Association for Cancer Research, 1425 K

St. NW., Washington, DC 20005, 267–765–1029, *Rasika.Kalamegham@aacr.org*.

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending the ''Complexities in Personalized Medicine: Harmonizing Companion Diagnostics Across a Class of Targeted Therapies'' public workshop must register online by March 17, 2015, 5 p.m. Registration will be handled through ASCO. Early registration is recommended because facilities are limited and, therefore, we 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 7 a.m.

If you need special accommodations due to a disability, please contact Kaitlyn Antonelli (see Contact Persons), 571–483–1606, *Kaitlyn.Antonelli@asco.org*, no later than March 10, 2015.

To register for the public workshop, please use the following Web site: *https://www.surveymonkey.com/s/FDACompanionDiagnostics2015*. Please provide complete contact information for each attendee, including name, title, affiliation, email, and telephone number. Those without Internet access should contact Kaitlyn Antonelli to register. Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Audiocast of the Public Workshop: This public workshop will also be audiocast. Persons interested in accessing the audiocast must register online using the following Web site: *https://www.surveymonkey.com/s/FDACompanionDiagnostics2015*. 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**. Early registration is recommended because audiocast connections are limited. Organizations are requested to register all participants but to view using one connection per location. After registration, participants will be sent technical system requirements and connection access information after March 19, 2015.

Comments: FDA is holding this public workshop to obtain information on harmonization of companion diagnostics across a class of targeted therapies. 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. The deadline for submitting comments related to this public workshop is April 23, 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. 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*.

Transcript: 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: Multiple manufacturers are developing therapeutic products that rely on a particular biomarker and that may require contemporaneous approval/clearance of a companion diagnostic if biomarker detection or measurement is necessary for the safe and effective use of the therapeutic product. Therapeutic product developers working in the same target space can use different methods and measures for the biomarker, and then partner with various sponsors to implement distinct companion diagnostics. These development programs can lead to approval/clearance of multiple therapeutic product-companion diagnostic pairs for a single class of therapeutic products. For example, understanding of the Programmed Death Ligand 1 (PD–1) checkpoint pathway underlies current development of multiple targeted therapies and potential companion diagnostics targeting and measuring PD–1 pathway biomarkers. Although the biomarker being detected/measured is the same (or closely related) within the drug class, there may be differences between the companion diagnostics in design and performance, such as use of different antibodies or different cut-off values leading to designation of different sets of marker-positive and marker-negative patients.

Comparison of the results from different tests is not part of the companies' development program for each drug/test pair. Likewise, differences in results from distinct tests are typically not examined for their effect on efficacy of products within the drug class. With no assurance that all the tests identify the populations most likely to respond to all of the drugs, problems may arise if various companion diagnostics for the same biomarker are used in clinical practice to direct treatment with all the targeted therapies in the drug class. Using multiple companion diagnostics to determine therapy for each patient is costly, inefficient, and challenging when dealing with a limited biological specimen. Even if it were practical, multiple testing might lead to suboptimal use of the drugs. Likewise, use of one companion diagnostic might not adequately inform the use of all of the targeted therapies. In such scenarios, where multiple targeted therapy-companion diagnostic pairs exist, patients may not be able to receive optimal care. FDA believes this is an important public health issue that is not easily resolved. Thus, FDA is convening this workshop in association with AACR and ASCO to foster a collaborative examination of the problem as it relates to various stakeholders and to identify potential solutions or paths to solutions for the problem.

Dated: March 3, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–05348 Filed 3–6–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections