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

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 Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Ancillary Study on IBD.

Date: April 8, 2015.

Time: 4:30 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Maria E. Davila-Bloom, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 758, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7637, *davila-bloomm@extra.niddk.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: March 3, 2015.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–05311 Filed 3–6–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Infant Mortality; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Advisory Committee on Infant Mortality (ACIM).

Dates and Times:

March 26, 2015, 8:30 a.m.–5:30 p.m.
March 27, 2015, 8:30 a.m.–3:30 p.m.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Status: The meeting is open to the public with attendance limited to space availability. For more details and registration, please visit the ACIM Web site: *http://www.hrsa.gov/advisorycommittees/mchbadvisory/InfantMortality/index.html.*

Purpose: The Committee provides advice and recommendations to the Secretary of Health and Human Services on the following: Department of Health and Human Services' programs that focus on reducing infant mortality and improving the health status of infants and pregnant women; and factors affecting the continuum of care with respect to maternal and child health care. The Committee focuses on outcomes following childbirth; strategies to coordinate myriad federal, state, local, and private programs and efforts that are designed to deal with the health and social problems impacting on infant mortality; and the implementation of the Healthy Start Program and *Healthy People 2020* infant mortality objectives.

Agenda: Topics that will be discussed include the following: HRSA Update; MCHB Update; Healthy Start Program Update; Updates from Partnering Agencies and Organizations; and, ACIM's recommendations for the HHS National Strategy to Address Infant Mortality, specifically Strategy 4: Increase Health Equity and Reduce Disparities by Targeting Social Determinants of Health through both Investments in High-Risk, Under-Resourced Communities and Major Initiatives to Address Poverty. Proposed agenda items are subject to change as priorities dictate.

Time will be provided for public comments limited to 5 minutes each. Comments are to be submitted in writing no later than 5:00 p.m. (EST) on March 19, 2015.

FOR FURTHER INFORMATION CONTACT: Anyone requiring information regarding the Committee should contact Michael C. Lu, M.D., M.P.H., Executive Secretary, ACIM, Health Resources and Services Administration, Room 18 W, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, telephone: (301) 443–2170.

Individuals who are submitting public comments or who have questions regarding the meeting and location should contact David S. de la Cruz, Ph.D., M.P.H., ACIM Designated Federal Official, HRSA, Maternal and Child Health Bureau, telephone: (301) 443–0543, or email: *David.delaCruz@hrsa.hhs.gov*.

Jackie Painter,

Director, Division of the Executive Secretariat.

[FR Doc. 2015–05416 Filed 3–6–15; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0913]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; 513(g) Request for Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by April 8, 2015.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0705. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

513(g) Request for Information—(OMB Control Number 0910–0705)—(Extension)

Section 513(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(g)) provides a means for obtaining the Agency's views about the classification and regulatory requirements that may be applicable to a particular device. Section 513(g) provides that, within 60 days of the receipt of a written request of any person for information respecting the class in which a device has been classified or the requirements applicable to a device under the FD&C Act, the Secretary of Health and Human Services