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

shall provide such person a written statement of the classification (if any) of such device and the requirements of the FD&C Act applicable to the device.

The guidance document entitled ''Guidance for Industry and Food and Drug Administration Staff; FDA and Industry Procedures for Section 513(g) Requests for Information Under the Federal Food, Drug, and Cosmetic Act'' establishes procedures for submitting, reviewing, and responding to requests for information respecting the class in which a device has been classified or the requirements applicable to a device under the FD&C Act that are submitted in accordance with section 513(g) of the FD&C Act. FDA does not review data related to substantial equivalence or safety and effectiveness in a 513(g) request for information. FDA's responses to 513(g) requests for information are not device classification decisions and do not constitute FDA clearance or approval for marketing. Classification decisions and clearance or approval for marketing require submissions under different sections of the FD&C Act. Additionally, the FD&C Act, as amended by the FDA Amendments Act of 2007 (Public Law 110–85), requires FDA to collect user fees for 513(g) requests for information. The guidance document entitled ''Guidance for Industry and Food and Drug Administration Staff; User Fees for 513(g) Requests for Information'' assists FDA staff and regulated industry by describing the user fees associated with 513(g) requests. The Medical Device User Fee Cover Sheet (Form FDA 3601), which accompanies the supplemental material described in this information collection, is approved under OMB control number 0910–0511 and expires April 30, 2016.

In the **Federal Register** of July 22, 2014 (79 FR 42517), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Center for Devices and Radiological Health 513(g) requests	114	1	114	12	1,368
Center for Biologics Evaluation and Research 513(g) requests	4	1	4	12	48
Total					1,416

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Respondents to this collection of information are mostly device manufacturers; however, anyone may submit a 513(g) request for information. The total number of annual responses is based on the average number of 513(g) requests received each year by the Agency.

Dated: March 2, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–05358 Filed 3–6–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0166]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Studies To Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Animals: Marker Residue Depletion Studies To Establish Product Withdrawal Periods; Revised Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised guidance for industry (GFI #207) entitled ''Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Animals: Marker Residue Depletion Studies to Establish Product Withdrawal Periods'' (VICH GL48(R)). This revised guidance, which provides minor updates to a final guidance on the same topic for which a notice of availability was published in the **Federal Register** of September 15, 2011 (2011 guidance), has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This revised VICH guidance is intended to provide study design recommendations that will facilitate the universal acceptance of the generated residue depletion data to fulfill the national/regional requirements.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the revised guidance to *http://www.regulations.gov.* Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Julia Oriani, Center for Veterinary Medicine (HFV–151), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0788, *julia.oriani@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical procedures for the development of pharmaceutical products. One of the goals of harmonization is to identify, and then reduce, differences in technical requirements for drug development among regulatory agencies in different countries.