5:30 p.m., and Thursday, November 20, 2014, from approximately 8:30 a.m. to 12:45 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Sections B and C, Silver Spring, Maryland 20993. For those unable to attend in person, the meeting will also be Web cast. The link for the Web cast is available at *https://collaboration.fda.gov/scienceboard.* Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Martha Monser, Office of the Chief Scientist, Office of the Commissioner, Food and Drug Administration, Bldg. 32, Rm. 4286, 10903 New Hampshire Ave., Silver Spring, Maryland 20993, 301–796–4627, *martha.monser@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On November 19, 2014, the Science Board will review the existing nonclinical and clinical data related to the use and potential toxicity of anesthetics and sedation drugs in the pediatric population. The Science Board will be asked to make recommendations on steps the FDA should take to further evaluate and to mitigate the risks associated with the use of these drugs in the pediatric population and mechanisms to best communicate with the public regarding this issue.

On November 20, 2014, the Science Board will be provided with progress reports from two subcommittees, the Commissioner's Fellowship Program Evaluation subcommittee and the Science Moving Forward subcommittee. The Board will be asked to support the formation of a new subcommittee to evaluate the Office of Regulatory Affairs' current investments in the Food Emergency Response Network cooperative agreement program and funding for state laboratories to achieve International Organization for Standardization accreditation. The Board will also be asked to support the formation of a new subcommittee to evaluate the Centers of Excellence in Regulatory Science and Innovation program. A recipient of one of the fiscal year 2013 Scientific Achievement Awards (selected by the Board) will provide an overview of the activities for which the award was given.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions pertaining to issues before the Board on November 19, 2014, may be made to the contact person on or before Wednesday, November 12, 2014. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on November 19, 2014. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before Tuesday, November 4, 2014. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak at the November 19, 2014, meeting by Wednesday, November 5, 2014.

Written submissions pertaining to issues before the Board on November 20, 2014, may be made to the contact person on or before Thursday, November 13, 2014. Oral presentations from the public will be scheduled between approximately 12 p.m. and 12:30 p.m. on November 20, 2014. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before Wednesday, November 5, 2014. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak at the November 20, 2014, meeting by Thursday, November 6, 2014.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Martha Monser at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 2, 2014.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2014–24001 Filed 10–7–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0967]

Prescription Drug User Fee Act Patient-Focused Drug Development; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment related to FDA's patient-focused drug development initiative. This initiative is being conducted to fulfill FDA performance commitments made as part of the fifth authorization of the Prescription Drug User Fee Act (PDUFA V). This effort provides for a more systematic approach under PDUFA V for obtaining the patient perspective on disease severity and currently available treatments for a set of disease areas. FDA is publishing a preliminary list of nominated disease areas for consideration in patient-focused drug development meetings during fiscal years (FYs) 2016–2017. The public is invited to comment on this preliminary list through a public docket.

DATES: Submit either electronic or written comments by December 5, 2014.

ADDRESSES: Submit electronic comments 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. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Pujita Vaidya, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1144, Silver Spring, MD 20993, 301–796–7641, FAX: 301–796–0684, *Pujita.Vaidya@fda.hhs.gov;* or Christopher Joneckis, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7316, Silver Spring, MD 20993–0002, 240–402–8083, *Christopher.Joneckis@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 2012, the President signed into law the Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012. Title I of FDASIA reauthorizes the Prescription Drug User Fee Act (PDUFA) that provides FDA with the necessary user fee resources to maintain an efficient review process for human drug and biologic products. The reauthorization of PDUFA includes performance goals and procedures that represent FDA's commitments during FYs 2013–2017. These commitments are referred to in section 101 of FDASIA and are available on the FDA Web site at *http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf*.

Section X of these commitments relates to enhancing benefit-risk assessment in regulatory decisionmaking. A key part of regulatory decisionmaking is establishing the context in which the particular decision is made. In drug regulation, this context includes a thorough understanding of the severity of the treated condition and the adequacy of the existing treatment options. Patients who live with a disease have a direct stake in the outcome of the review process and are in a unique position to contribute to weighing benefit-risk considerations that can occur throughout the medical product development process. Though several programs exist to facilitate patient representation, there are currently few venues in which the patient perspective is discussed outside of a specific product's marketing application review. The human drug and biologic review process could benefit from a more systematic and expansive approach to obtaining input from patients who experience a particular disease or condition.

FDA is committed to obtaining the patient perspective on 20 different disease areas during the course of PDUFA V (FY 2013–2017). For each disease area, the Agency is conducting a public meeting to discuss the disease, its impact on patients' daily lives, the types of treatment benefit that matter most to patients, and patients' perspectives on the adequacy of available therapies. These meetings include participation of FDA review divisions, the relevant patient community, and other interested stakeholders.

On April 11, 2013, FDA published a **Federal Register** notice (78 FR 21613) announcing the disease areas for meetings in FYs 2013–2015, the first 3 years of PDUFA V. In selecting the set of disease areas, FDA carefully considered the public comments received and the perspectives of review divisions at FDA. FDA is initiating a second public process for determining the disease areas for FYs 2016–2017. A preliminary list of possible disease areas and the criteria used to identify these disease areas are published in this document for public comment. FDA will consider the public comments received through the public docket and publish the set of disease areas for FYs 2016–2017 in a **Federal Register** notice.

II. Disease Area Nomination

FDA is nominating the following disease areas as potential candidates for the focus of the remaining public meetings in FYs 2016–2017 and invites public comment on this preliminary list. In your comments, please identify the disease areas that you consider to be of greatest priority and explain the rationale for your recommendation.

- Achondroplasia
- Alopecia areata
- Autism
- Autoimmune disorders treated with immune globulins
- Depression
- Diabetic foot infection
- Hereditary angiodema
- Melanoma, specifically unresectable loco-regional disease
- Neurologic disorders treated with immune globulins
- Nontuberculous mycobacterial infections
- Ovarian cancer
- Patients who have received an organ transplant
- Primary humoral immune deficiencies
- Pruritis
- Sarcopenia
- Thrombotic disorders

FDA is also interested in public comment on disease areas that are not represented on this preliminary list. The Agency used several criteria to develop the preliminary list of potential disease areas. In the series of disease area meetings, the final disease set should reflect a range of diseases with respect to disease severity (less severe to more severe) and represent a broad range in terms of the size of the affected population (e.g., including more prevalent diseases as well as rare diseases). FDA requests that when proposing additional disease areas for consideration, please describe how you applied the identified criteria in making recommendations for additional disease areas to consider. The criteria include the following:

- Disease areas that are chronic, symptomatic, or affect functioning and activities of daily living;
- disease areas for which aspects of the disease are not formally captured in clinical trials;
- disease areas for which there are currently no therapies or very few therapies, or the available therapies do not directly affect how a patient feels, functions, or survives; and
- disease areas that have a severe impact on identifiable subpopulations (such as children or the elderly).

III. 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*.

Dated: October 2, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–23965 Filed 10–7–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-day Comment Request; a Generic Submission for Theory Development and Validation (NCI)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on July 14, 2014, Vol. 79, page 40763 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Cancer Institute (NCI), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: NIH Desk Officer.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: Rebecca A. Ferrer, Division of Cancer Control and Population Sciences, 9609 Medical Center Dr., Room 3E114, Bethesda, MD 20892 or call non-toll-free number 240–276–6914 or Email your request, including your address to: *ferrerra@mail.nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: A Generic Submission for Theory Development and Validation (NCI), Revision, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The National Cancer Institute is requesting approval for this revised generic clearance to conduct formative research related to behavioral science theory development and validation for the next three years. Formative research in the area of theory development and validation would provide the basis for developing effective cancer prevention and control strategies, allow for a better understanding of theoretical constructs that influence decisions and actions related to cancer, and ultimately contribute to reducing the U.S. cancer burden. Sub-studies proposed under this generic clearance would involve methodological testing and a standard set of research approaches, including surveys (internet, phone, and paper-and-pencil) and focus groups. Respondents would include individuals in the general public, recruited through established online panels or internet/newspaper advertisements. Development of each study or survey would involve consulting with NCI scientists as well as experts from the behavioral science research community.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated burden is 2,000 hours per year.

Estimated Burden Hours for Three Years

TABLE A.12–1—ESTIMATES OF ANNUAL BURDEN HOURS

Type of respondents	Number of respondents	Frequency of response	Average time per response (minutes/hour)	Total burden hours
General Public	667	1	15/60	167
Physicians	2,000	1	30/60	1,000
Health Professionals	333	1	1	333
Researchers	333	1	90/60	500

Dated: October 1, 2014.

Karla Bailey,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2014–23999 Filed 10–7–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Application Forms for Research Development and Training Grants

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 collections via application forms, the National Institute on Drug Abuse (NIDA), the National Institutes of Health (NIH) will publish periodic summaries of proposed collections 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