

and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance 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:**

Alicia Barbieri Stuart, Office of Translational Sciences, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, Rm. 4547, Silver Spring, MD 20993-0002, 301-796-3852.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a guidance for industry entitled "Critical Path Innovation Meetings." The guidance describes the purpose and scope of a CPIM and how to request such a meeting. A CPIM provides the opportunity to discuss a methodology or technology proposed by the meeting requester and for CDER to provide general advice on how the methodology or technology might enhance drug development. During a CPIM, CDER will identify some of the larger gaps in existing knowledge that requesters might consider addressing in the course of their work. The discussions and background information submitted through the CPIM are nonbinding on both FDA and CPIM requesters. The CPIM initiative meets Prescription Drug User Fee Act (PDUFA) V Reauthorization Goal IX.A, "Enhancing Regulatory Science and Expediting Drug Development" by "Promoting Innovation Through Enhanced Communication Between FDA and Sponsors During Drug Development."

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Critical Path Innovation Meetings." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

**II. The Paperwork Reduction Act of 1995**

This guidance refers to previously approved collections of information that

are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collection of information in 21 CFR part 312 (investigational new drug applications) has been approved under OMB control number 0910-0014. The collection of information in 21 CFR part 314 (new drug applications) has been approved under OMB control number 0910-0001. The collection of information resulting from formal meetings between interested persons and FDA has been approved under OMB control number 0910-0429.

**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>.

**IV. Electronic Access**

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/Guidance/ComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: March 24, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015-07272 Filed 3-30-15; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2015-N-0001]

**Pulmonary-Allergy Drugs Advisory Committee; Notice of Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Pulmonary-Allergy Drugs Advisory Committee.

*General Function of the Committee:* To provide advice and

recommendations to the Agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on May 12, 2015, from 8 a.m. to 4 p.m.

*Location:* Hilton Washington DC North/Gaithersburg, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel phone number is 301-977-8900.

*Contact Person:* Cindy Hong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, email: [PADAC@fda.hhs.gov](mailto:PADAC@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:* The committee will discuss new drug application (NDA) 206038, lumacaftor/ivacaftor combination tablets for oral use, submitted by Vertex Pharmaceuticals, proposed for the treatment of cystic fibrosis (CF) in patients age 12 years and older who are homozygous for the *F508del* mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.

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 meeting link.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before April 27, 2015. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. 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 April 17, 2015. 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 by April 20, 2015.

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 Cindy Hong 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: March 25, 2015.

**Jill Hartzler Warner,**

*Associate Commissioner for Special Medical Programs.*

[FR Doc. 2015-07299 Filed 3-30-15; 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 Meetings

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 meetings.

The meetings 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; Time-Sensitive Obesity.

*Date:* April 27, 2015.

*Time:* 12:00 p.m. to 2:00 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:* Michele L. Barnard, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 753, 6707 Democracy Boulevard, Bethesda, MD 20892-2542, (301) 594-8898, [barnardm@extra.niddk.nih.gov](mailto:barnardm@extra.niddk.nih.gov)

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Pragmatic Research and Natural Experiments.

*Date:* May 6, 2015.

*Time:* 10:00 a.m. to 2:00 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:* Michele L. Barnard, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 753, 6707 Democracy Boulevard, Bethesda, MD 20892-2542, (301) 594-8898, [barnardm@extra.niddk.nih.gov](mailto:barnardm@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 25, 2015.

**David Clary,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2015-07255 Filed 3-30-15; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Community Living

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Extension of Certification of Maintenance of Effort on Help America Vote Act, Payments for Protection and Advocacy Systems (P&A Voting Access Narrative Annual Report)

**AGENCY:** Administration on Intellectual and Developmental Disabilities, Administration for Community Living, HHS.

**ACTION:** Notice.

**SUMMARY:** The Administration for Community Living (ACL) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements relating to the Help America Vote Act (HAVA), Public Law 107-252, title II, subtitle D, section 291, Payments for Protection and Advocacy Systems (P&As Narrative Annual Report).

**DATES:** Submit written or electronic comments on the collection of information by June 1, 2015.

**ADDRESSES:** Submit electronic comments on the collection of information to: [melvenia.wright@acl.hhs.gov](mailto:melvenia.wright@acl.hhs.gov).

Submit written comments on the collection of information to Administration for Community Living, 1 Massachusetts Avenue NW., Room 4716, Washington, DC 20001, attention Melvenia Wright.

**FOR FURTHER INFORMATION CONTACT:** Melvenia Wright, Program Specialist, Administration for Community Living, Washington, DC 20001. Telephone: (202) 357-3486; email [melvenia.wright@acl.hhs.gov](mailto:melvenia.wright@acl.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency request or requirements that members of the