Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2017–17699 Filed 8–21–17; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Application Requirements for the Low Income Home Energy Assistance Program (LIHEAP) Plan.

OMB No.: 0970–0075.

Description: States, including the District of Columbia, tribes, tribal organizations, and U.S. territories applying for LIHEAP block grant funds must, prior to receiving federal funds, submit an annual application (Model Plan, ACF–122) that meets the LIHEAP statutory and regulatory requirements. In addition to the Model Plan, grantees are also required to complete the Mandatory Grant Application SF–424–Mandatory, which is the first section of the Model Plan.

The LIHEAP Model Plan is an electronic form and is submitted to the Administration for Children and Families (ACF), Office of Community Services (OCS) through the On-line Data Collection (OLDC) system within GrantSolutions, which is currently being used by all LIHEAP grantees to submit other required LIHEAP reporting forms. In order to reduce the reporting burden, all data entries from each grantee's prior year's submission of the Model Plan in OLDC is saved and re-populated (cloned) into the form for the following fiscal year's application.

OCS seeks renewal of this form without any changes. A sample model plan showing these proposed changes can be found on the U.S. Department of Health and Human Services, ACF/OCS LIHEAP Program Resources page at: *https://www.acf.hhs.gov/ocs/resource/funding-applications.*

On April 3, 2017, ACF published a **Federal Register** Notice seeking 60 days of public comment on this proposed information collection. One state grantee provided comments. ACF revised the Plan to address the comments by ensuring that open field boxes and attachment capability are available if the answer choices are insufficient to address the questions.

The revised model plan can be viewed on the OCS Web site at: *http://www.acf.hhs.gov/programs/ocs/programs/liheap.*

Respondents: State, the District of Columbia, U.S. Territories and Tribal governments.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
LIHEAP Detailed Model Plan	210	1	0.50	105

Estimated Total Annual Burden Hours (all respondents): 105.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington, DC 20201. Attention Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2017–17681 Filed 8–21–17; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–4885]

Pediatric Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) announces a forthcoming public advisory committee meeting of the Pediatric Advisory Committee (PAC). The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comments.

DATES: The meeting will be held on September 11, 2017, from 8:30 a.m. to 5:30 p.m. and September 12, 2017, from 8:30 a.m. to 1 p.m.

ADDRESSES: Hilton Washington DC/Rockville Hotel & Executive Meeting Center, 1750 Rockville Pike, Rockville, MD 20852. The hotel's telephone number is 301–468–1100. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at *http://www3.hilton.com/en/hotels/maryland/hilton-washington-dc-rockville-hotel-and-executive-meeting-ctr-IADMRHF/index.html.*

FDA is establishing a docket for public comment on this document. The docket number is FDA–2017–N–4885. The docket will close on September 13, 2017. Submit either electronic or written comments on this public meeting by that date. Late, untimely comments will not be considered. Electronic comments must be submitted on or before September 13, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of September 13, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before August 28, 2017, will be provided to the committee. Comments received after that date will be taken into consideration by FDA.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to make available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–N–4885 for ''Pediatric Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Marieann Brill, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5154, Silver Spring, MD 20993, 240–402–3838, *marieann.brill@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.* 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.

SUPPLEMENTARY INFORMATION:

Agenda: The PAC will meet to discuss pediatric-focused safety reviews, as mandated by the Best Pharmaceuticals for Children Act (Pub. L. 107–109) and the Pediatric Research Equity Act (Pub. L. 108–155). Comments about the upcoming September advisory committee meeting should be submitted to Docket No. FDA–2017–N–4885.

On September 11, 2017, the PAC will discuss the use of prescription opioid products containing hydrocodone or codeine for the treatment of cough in pediatric patients. The discussion will include current practice for the treatment of cough in children and benefit-risk considerations regarding the use of prescription opioid products in pediatric patients.

On September 12, 2017, the PAC will meet to discuss the following products (listed by FDA Center):

(1) Center for Drug Evaluation and Research
   a. ABILIFY (aripiprazole)
   b. KEPPRA/KEPPRA XR (levetiracetam)
(2) Center for Devices and Radiological Health
   a. CONTEGRA Pulmonary Valved Conduit (humanitarian device exemption (HDE)
   b. ENTERRA Therapy System (HDE)
   c. PLEXIMMUNE (HDE)
   d. ELANA Surgical Kit (HDE)

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 will be 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 September 5, 2017. Oral presentations from the public will be scheduled on September 11, 2017, between approximately 1 p.m. and 2 p.m. and on September 12, 2017, between approximately 9 a.m. and 10 a.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 August 25, 2017. 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 August 28, 2017.

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

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Marieann Brill 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: August 17, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–17726 Filed 8–21–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0062]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices; Exception From General Requirements for Informed Consent

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) 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 September 21, 2017.

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 0910–0586. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

Medical Devices; Exception From General Requirements for Informed Consent OMB Control Number 0910–0586—Extension

In the **Federal Register** of June 7, 2006 (71 FR 32827), FDA issued an interim final rule to amend its regulations to establish a new exception from the general requirements for informed consent, to permit the use of investigational in vitro diagnostic devices to identify chemical, biological, radiological, or nuclear agents without informed consent in certain circumstances. The Agency took this action because it was concerned that, during a potential terrorism event or other potential public health emergency, delaying the testing of specimens to obtain informed consent may threaten the life of the subject. In many instances, there may also be others who have been exposed to, or who may be at risk of exposure to, a dangerous chemical, biological, radiological, or nuclear agent, thus necessitating identification of the agent as soon as possible. FDA created this exception to help ensure that individuals who may have been exposed to a chemical, biological, radiological, or nuclear agent are able to benefit from the timely use of the most appropriate diagnostic devices, including those that are investigational.

Section 50.23(e)(1) (21 CFR 50.23(e)(1)) provides an exception to the general rule that informed consent is required for the use of an investigational in vitro diagnostic device. This exception applies to those situations in which the in vitro investigational diagnostic device is used to prepare for, and respond to, a chemical, biological, radiological, or nuclear terrorism event or other public health emergency, if the investigator and an independent licensed physician make the determination and later certify in writing that: (1) There is a life-threatening situation necessitating the use of the investigational device, (2) obtaining informed consent from the subject is not feasible because there was no way to predict the need to use the investigational device when the specimen was collected and there is not sufficient time to obtain consent from the subject or the subject's legally authorized representative, and (3) no satisfactory alternative device is available. Under the rule, these determinations are made before the device is used, and the written certifications are made within 5 working days after the use of the device. If use of the device is necessary to preserve the life of the subject and there is not sufficient time to obtain the determination of the independent licensed physician in advance of using the investigational device, § 50.23(e)(2) provides that the certifications must be made within 5 working days of use of the device. In either case, the certifications are submitted to the Institutional Review Board (IRB) and, under § 50.23(e)(3) (76 FR 36989, June 24, 2011), to FDA within 5 working days of the use of the device.

Section 50.23(e)(4) provides that an investigator must disclose the investigational status of the device and what is known about the performance characteristics of the device at the time test results are reported to the subject's health care provider and public health authorities, as applicable. Under § 50.23(e)(4), the investigator provides the IRB with the information required by § 50.25 (21 CFR 50.25) (except for the information described in § 50.25(a)(8)) and the procedures that will be used to provide this information to each subject or the subject's legally authorized representative.

FDA estimates that there are approximately 150 laboratories that could perform testing that uses investigational in vitro diagnostic devices to identify chemical, biological, radiological, or nuclear agents. FDA estimates that in the United States each year there are approximately 450