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: Joseph G. Toerner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6244, Silver Spring, MD 20993–0002, 301–796–1300.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Neglected Tropical Diseases of the Developing World: Developing Drugs for Treatment or Prevention.'' The purpose of this guidance is to assist sponsors in the development of drugs for the treatment or prevention of NTDs as defined in section 524(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360n(a)(3)).

NTDs are infectious diseases that are generally rare or absent in developed countries, but are often widespread in developing countries. The availability of new drugs that are safe and effective for treatment or prevention of NTDs could provide public health benefit for overall global health.

This guidance addresses general issues in drug development and implementation of clinical trials for NTDs. FDA will review and comment on drug development plans and will review new drug applications or biologics license applications for new drugs for NTDs, regardless of where the clinical development program takes place. Specifically, the guidance provides a general overview of nonclinical development considerations, as well as clinical development considerations and regulatory paradigms. Other activities in the Center for Drug Evaluation and Research that pertain to NTDs are summarized in the guidance. Listings of guidance documents that are most relevant to drug development for NTDs are included in the guidance.

This guidance finalizes the draft guidance issued August 24, 2011. Comments on the draft guidance were considered while finalizing this guidance. Specifically, changes from the draft guidance include descriptions of new regulatory designations (Qualified Infectious Disease Product; Breakthrough Therapy).

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on developing drugs for the treatment or prevention of neglected tropical diseases of the developing world. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach 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 collections of information in 21 CFR part 312 and 21 CFR part 314 have been approved under OMB control numbers 0910–0014 and 0910–0001.

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/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: July 1, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–15801 Filed 7–3–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Pediatric 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: Pediatric 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 September 23, 2014, from 8 a.m. to 5:30 p.m.

Location: Bethesda Marriott, 5151 Pooks Hill Rd., Bethesda, MD 20814.

Contact Person: Walter Ellenberg, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5154, Silver Spring, MD 20993–0002, 301–796–0885, 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 link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The Pediatric Advisory Committee will meet to discuss pediatric-focused safety reviews, as mandated by the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act for: AFINITOR DISPERZ (everolimus); Berlin Heart EXCOR® Pediatric Ventricular Assist Device; CONTEGRA® Pulmonary Valved Conduit; DYMISTA (azelastine hydrochloride; fluticasone propionate); Elana Surgical Kit; ENTERRA Therapy System; LEVAQUIN (levofloxacin); LEXIVA (fosamprenavir calcium); QNASL (beclomethasone diproprionate), Medtronic Melody® Transcatheter Pulmonary Valve; MENHIBRIX (Meningococcal Groups C and Y and Haemophilus b Tetanus Toxoid Conjugate Vaccine); SINGULAIR (montelukast sodium); TREANDA (bendamustine hydrochloride); VERAMYST (fluticasone furoate); VIREAD (tenofovirdisoproxil fumarate); and VOLUVEN (6% hydroxyethyl starch 130/0.4 in 0.9% sodium chloride injection).

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 may be made to the contact person on or before August 25, 2014. Oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12:30 p.m. on September 23, 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 August 15, 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 by August 18, 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 Walter Ellenberg 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: June 30, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–15683 Filed 7–3–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Ryan White HIV/AIDS Program, AIDS Education and Training Centers, Graduate Medical Education Grant Under the Ryan White HIV/AIDS Program

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice of a Class Deviation from Competition Requirements for the HIV/AIDS Bureau's (HAB) Ryan White HIV/AIDS Program, AIDS Education and Training Centers (AETC), Graduate Medical Education (GME) Program (H4A).

SUMMARY: HRSA will be issuing non-competitive awards under the Ryan White HIV/AIDS Program, AETC/GME Program. Approximately $450,000 will be made available in the form of a grant to current grantees (listed in chart below) during the budget period of July 1, 2014, through June 30, 2015. This will: (1) Continue the current cohort and provide support for one additional cohort of graduate medical residents; (2) continue to provide workforce development that is integral to the national interest through meeting National HIV/AIDS Strategy goals, and that enhances the implementation of the Affordable Care Act; and (3) provide a more robust program evaluation that will yield sufficient data; and aid HRSA/HAB in future decisions regarding the replication and the viability of a subsequent GME competition. The scope of work does not change.

SUPPLEMENTARY INFORMATION: Intended recipients of the awards are the three incumbent grantees of record (listed in chart below). The amount of the non-competitive awards is $150,000 per grantee.

Authority: Section 2692 of the Public Health Service Act, 42, U.S.C. 300ff–111.

CFDA Number: 93.145

Project period: July 1, 2014, through June 30, 2015.

Justification: The GME Program, which has three funded grantees: Yale University (H4AHA22762), Research Foundation of the State University of New York (H4AHA22761), and Family Medicine Residency of Idaho (H4AHA22760), is scheduled to end June 30, 2014. The Ryan White HIV/AIDS AETC/GME Program seeks to provide a one-time non-competitive award in order to avoid interruption in continued HIV primary medical care education at these three universities by completing the current cohort and producing one more cohort of graduates, thus providing additional time to accurately assess and evaluate the success of the program. This is a primary care training group, which helps link critical HIV/AIDS resources within and across communities to help expand the clinician workforce capacity to meet the growing demand for HIV care by training their medical residents. The purpose of the GME program (which ties directly to the shortage of primary health care providers in HIV/AIDS care in the United States) is to fund public and nonprofit private entities and schools, and academic health science centers in order to expand opportunities to train medical residents in HIV/AIDS care and treatment. Grant funds are requested in order to accomplish this purpose and meet the three objectives described in the above summary. This funding is intended to bridge the gap until this GME program may be competed again.

FOR FURTHER INFORMATION CONTACT: Diana Travieso Palow, Branch Chief, HIV Education Branch, Division of Training and Capacity Development, HAB/HRSA 5600 Fishers Lane, Rockville, MD 20857, by email at *DPalow@hrsa.gov*, or by phone at (301) 443–4405.

Grantee/organization name	Grant No.	State	FY 2014 Supplemental funding	Revised project end date
Yale University	H4AHA22762	CT	$150,000	June 30, 2015.
Research Foundation of the State University of New York (SUNY)	H4AHA22761	NY	150,000	June 30, 2015.
Family Medicine Residency of Idaho	H4AHA22760	ID	150,000	June 30, 2015