vote in the selection process. Persons who nominate themselves to serve as voting or nonvoting consumer representatives will not participate in the selection process.

Dated: September 25, 2015.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2015–24835 Filed 9–30–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Pharmacy Compounding 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: Pharmacy Compounding Advisory Committee.

General Function of the Committee: To provide advice on scientific, technical, and medical issues concerning drug compounding under sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act), and, as required, any other product for which FDA has regulatory responsibility, and make appropriate recommendations to the Commissioner of Food and Drugs.

Date and Time: The meeting will be held on October 27, 2015, from 8 a.m. to 5:30 p.m., and on October 28, 2015, from 8:30 a.m. to 4:45 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

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: *PCAC@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.

Background: Section 503A of the FD&C Act (21 U.S.C. 353a) describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist or licensed physician to be exempt from the following three sections of the FD&C Act: (1) Section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice); (2) section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use); and (3) section 505 (21 U.S.C. 355) (concerning the approval of human drug products under new drug applications (NDAs) or abbreviated new drug applications (ANDAs)).

The Drug Quality and Security Act adds a new section, 503B, to the FD&C Act (21 U.S.C. 353b) that creates a new category of ''outsourcing facilities.'' Outsourcing facilities, as defined in section 503B of the FD&C Act, are facilities that meet certain conditions described in section 503B, including registration with FDA as an outsourcing facility. If these conditions are satisfied, a drug product compounded for human use by or under the direct supervision of a licensed pharmacist in an outsourcing facility is exempt from three sections of the FD&C Act: (1) Section 502(f)(1), (2) section 505, and (3) section 582 (21 U.S.C. 360eee–1), but not section 501(a)(2)(B).

One of the conditions that must be satisfied to qualify for the exemptions under both sections 503A and 503B of the FD&C Act is that the drug that is compounded does not appear on a list published by the Secretary of Health and Human Services (the Secretary) of drugs that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective (''withdrawn or removed list'') (see sections 503A(b)(1)(C) and 503B(a)(4) of the FD&C Act).

Another condition that must be satisfied to qualify for the exemptions under section 503A of the FD&C Act is that a bulk drug substance (active pharmaceutical ingredient) used in a compounded drug must meet one of the following criteria: (1) Complies with the standards of an applicable United States Pharmacopoeia (USP) or National Formulary monograph, if a monograph exists, and the USP chapter on pharmacy compounding; (2) if an applicable monograph does not exist, is a component of a drug approved by the Secretary; or (3) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, appears on a list (''section 503A bulk drug substances list'') developed by the Secretary through regulations issued by the Secretary (see section 503A(b)(1)(A)(i) of the FD&C Act).

FDA will discuss with the committee drugs proposed for inclusion on the withdrawn or removed list pursuant to sections 503A and 503B of the FD&C Act and on the section 503A bulk drug substances list.

Agenda: On October 27, 2015, during the morning session, the committee will discuss a revision FDA is considering to the list of drug products that may not be compounded under the exemptions provided by the FD&C Act because the drug product has been withdrawn or removed from the market because such drug product or such components of drug products have been found to be unsafe or not effective. The list of those drug products is currently codified at 21 CFR 216.24. FDA now is considering whether to amend the regulation to add one more drug to the list: Quinacrine: All drug products containing quinacrine for intrauterine administration. As explained in the **Federal Register** of July 2, 2014, (79 FR 37687 at 37689 through 37690), the list may specify that a drug may not be compounded in any form, or, alternatively, may expressly exclude a particular formulation, indication, dosage form, or route of administration from an entry on the list because an approved drug containing the same active ingredient(s) has not been withdrawn or removed from the market. Moreover, a drug may be listed only with regard to certain formulations, indications, routes of administration, or dosage forms because it has been found to be unsafe or not effective in those particular formulations, indications, routes of administration, or dosage forms. FDA plans to seek the committee's advice concerning the inclusion of this drug product.

On October 27, 2015, during the morning and afternoon sessions, the committee will discuss six bulk drug substances nominated for inclusion on the section 503A bulk drug substances

list. FDA intends to discuss the following nominated bulk drug substances: Quinacrine hydrochloride, methylsulfonylmethane, curcumin, germanium sesquioxide, rubidium chloride, and deoxy-D-glucose. The nominators of these substances will be invited to make a short presentation supporting the nomination.

On October 28, 2015, during the morning and afternoon sessions, the committee will discuss four bulk drug substances nominated for inclusion on the section 503A bulk drug substances list. FDA intends to discuss the following nominated bulk drug substances: Alanyl-L-glutamine, glutaraldehyde, glycyrrhizin, and domperidone. Other nominated substances will be discussed at future committee meetings.

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 October 13, 2015. Oral presentations from the public will be scheduled between approximately 9:45 a.m. to 10 a.m., 1:30 p.m. to 1:45 p.m., and 4:15 p.m. to 4:30 p.m. on October 27, 2015, and between approximately 11 a.m. to 11:15 a.m. and 2:45 p.m. to 3:30 p.m. on October 28, 2015. 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 October 9, 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 October 13, 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 disabilities. If you require 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: September 25, 2015.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2015–24834 Filed 9–30–15; 8:45 am]

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Notice of Class Deviation From Competition Requirements

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

ACTION: Notice of Class Deviation from Competition Requirements: Program Expansion Supplement Request for Pediatric Audiology Supplements to ten Leadership Education in Neurodevelopmental and Other Related Disabilities (LEND) Maternal and Child Health (MCH) Training Programs.

SUMMARY: HRSA announces the award of a program expansion supplement in the amount of $70,000 each to ten Leadership Education in Neurodevelopment and Other Related Disabilities (LEND) grantees with existing graduate-level pediatric audiology programs. The purpose of the LEND Program is to enhance the clinical expertise and leadership skills of professionals dedicated to caring for children with neurodevelopmental and other related disabilities, including autism, and to increase the number of trained providers available to treat children with complex disabilities. The purpose of this notice is to award a 12-month supplement to LEND pediatric audiology programs to: (1) Strengthen the focus on testing for hearing loss in young infants and children with autism spectrum disorder (ASD) and other related neurodevelopmental disabilities (DD); and (2) to increase the number of pediatric audiology trainees with clinical and leadership skills to detect hearing loss in these infants/children, and to develop systems to increase enrollment of identified infants/children into early intervention programs.

SUPPLEMENTARY INFORMATION:

Intended Recipients of the Awards: University of Utah, UNC-Chapel Hill, University of Pittsburgh, University of Colorado, Vanderbilt University, University of Miami, University of South Dakota, University of Washington, Children's Hospital Boston, University of Wisconsin.

Amount of Each Non-Competitive Award: $70,000.

Period of Supplemental Funding: 7/1/2015–6/30/2016.

CFDA Number: 93.110.

Authority: Autism Act of 2006, Public Health Service (PHS) Act § 399BB(e)(1)(A), codified at 42 U.S.C. 280i–1.

Justification: The ten LEND programs discussed in this request are currently in year 5 of a 5-year project period. Approval of this request for a $70,000 program expansion supplement to each of the ten grantees will allow the programs to continue their work to strengthen the focus on testing for hearing loss in young infants and children with ASD and other related DD, to increase the number of pediatric audiology trainees with clinical and leadership skills to detect hearing loss in these infants/children, and to enroll identified infants/children into early intervention programs.

The identified LEND grantees are uniquely qualified to perform the expanded activity because for the past 6 years they have provided enhanced didactic and clinical training in pediatric audiology and have increased the number of trained pediatric audiologists to provide critical services in the community. If these grantees are awarded a program expansion, LEND will continue to increase the number of pediatric audiology trainees with clinical and leadership skills to detect hearing loss in infants/children with ASD and other related DD, and to enroll identified infants/children into early intervention programs. Each of the ten LEND Programs that receive this funding has made a commitment to