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]

BILLING CODE 4164–01–P

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

three to four pediatric audiology trainees in their programs. Without a continuation of funds, the trainees will be left with an incomplete training experience. Disapproval of this request may also prevent families of children with ASD and other DD from receiving appropriate services through trained providers and create more burden on families to access early intervention services in a timely manner.

FOR FURTHER INFORMATION CONTACT: Denise Sofka, RD, MPH, Division of Maternal and Child Health Workforce Development, Maternal and Child Health Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 18W55, Rockville, Maryland 20857; *DSofka@hrsa.gov.* Robyn J. Schulhof, MA, Division of Maternal and Child Health Workforce Development, Maternal and Child Health Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 18W50, Rockville, Maryland 20857; *RSchulhof@hrsa.gov.*

Grantee/organization name	Grant No.	State	Current project start date	Current project end date	Fiscal year 2014 authorized funding level	Fiscal year 2015 estimated funding level
University of Colorado	T73MC11044	CO	7/1/2011	6/30/2016	$544,765	$614,765
University of Miami	T73MC00013	FL	7/1/2011	6/30/2016	712,385	782,385
Children's Hospital Boston	T73MC00020	MA	7/1/2011	6/30/2016	670,480	740,480
UNC-Chapel Hill	T73MC00030	NC	7/1/2011	6/30/2016	833,174	903,174
University of Pittsburgh	T73MC00036	PA	7/1/2011	6/30/2016	586,452	656,452
University of South Dakota	T73MC00037	SD	7/1/2011	6/30/2016	529,942	599,942
Vanderbilt University	T73MC00050	TN	7/1/2011	6/30/2016	577,381	648,289
University of Utah	T73MC00054	UT	7/1/2011	6/30/2016	747,435	817,435
University of Washington	T73MC00041	WA	7/1/2011	6/30/2016	814,466	884,466
University of Wisconsin	T73MC00044	WI	7/1/2011	6/30/2016	658,569	734,054

Dated: September 24, 2015.

James Macrae,

Acting Administrator.

[FR Doc. 2015–24965 Filed 9–30–15; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by Section 2112(b)(2) of the Public Health Service (PHS) Act, as amended. While the Secretary of Health and Human Services is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact the Clerk, United States Court of Federal Claims, 717 Madison Place NW., Washington, DC 20005, (202) 357–6400. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 11C–26, Rockville, MD 20857; (301) 443–6593, or visit our Web site at: *http://www.hrsa.gov/vaccinecompensation/index.html.*

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa–10 *et seq.,* provides that those seeking compensation are to file a petition with the U.S. Court of Federal Claims and to serve a copy of the petition on the Secretary of Health and Human Services, who is named as the respondent in each proceeding. The Secretary has delegated this responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at 42 CFR 100.3. This Table lists for each covered childhood vaccine the conditions that may lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in the Table and for conditions that are manifested outside the time periods specified in the Table, but only if the petitioner shows that the condition was caused by one of the listed vaccines.

Section 2112(b)(2) of the PHS Act, 42 U.S.C. 300aa–12(b)(2), requires that ''[w]ithin 30 days after the Secretary receives service of any petition filed under section 2111 the Secretary shall publish notice of such petition in the **Federal Register**.'' Set forth below is a list of petitions received by HRSA on August 1, 2015, through August 31, 2015. This list provides the name of petitioner, city and state of vaccination (if unknown then city and state of person or attorney filing claim), and case number. In cases where the Court has redacted the name of a petitioner and/or the case number, the list reflects such redaction.

Section 2112(b)(2) also provides that the special master ''shall afford all interested persons an opportunity to submit relevant, written information'' relating to the following:

1. The existence of evidence ''that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition,'' and

2. Any allegation in a petition that the petitioner either:

a. ''[S]ustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by'' one of the vaccines referred to in the Table, or

b. ''[S]ustained, or had significantly aggravated, any illness, disability,