metabolism, a cure does not exist, and treatment focuses on prevention and management of signs and symptoms.

The questions that will be asked of patients and patient stakeholders at the meeting are listed in this section, organized by topic. For each topic, a brief initial patient panel discussion will begin the dialogue and will be followed by a facilitated discussion inviting comments from other patient and patient stakeholder participants. In addition to input generated through this public meeting, FDA is interested in receiving patient input addressing these questions through written comments, which can be submitted to the public docket (see **ADDRESSES**).

For the purposes of this Patient-Focused Drug Development Meeting, FDA is interested in hearing from patients specifically about the neurologic/neuropsychological aspects of inborn errors of metabolism.

For context, please indicate if you are commenting on behalf of a child or loved one who has an inborn error of metabolism. If you are commenting on behalf of a child or loved one, please answer the following questions as much as possible from the patient's perspective.

Topic 1: Disease Signs, Symptoms, and Daily Impacts That Matter Most to Patients

1. Of all the signs or symptoms that you/your child experiences because of the condition, which 1–3 neurologic/neuropsychological signs and/or symptoms have the most significant impact on your/your child's life? (Examples may include seizures, decreased muscle tone, sensory issues, etc.)

2. Are there specific activities that are important to you/your child but that you/your child cannot do because of these neurologic/neuropsychological signs or symptoms? (Examples of activities may include sleeping through the night, daily hygiene, going up the stairs, etc.)

3. How have your/your child's neurologic/neuropsychological signs or symptoms changed over time?

Topic 2: Patient Perspectives on Current Approaches to Treating Neurologic Manifestations of Inborn Errors of Metabolism

1. What are you/your child currently doing to help treat the condition or its signs/symptoms? (Examples may include prescription medicines, herbal therapies, acupuncture, over-the-counter products, and other therapies including nondrug therapies such as diet modification.)

How well does this current treatment regimen treat the neurological symptoms of your/your child's disease? For example, how well do the treatments improve your/your child's ability to do specific activities?

2. Assuming there is no complete cure for your/your child's condition, what specific attributes would you look for in an ideal treatment for the condition?

3. The process of informed consent is an important way for researchers to communicate the purpose of a clinical trial and the potential benefits and risks of the trial so that people can make an informed decision about whether to participate. Informed consent also ensures that parents are fully informed and are given opportunities to ask questions about the clinical trial. In addition to informed consent from parents, assent from children may also be needed. Assent is the term used to describe when a child agrees to be in a clinical trial. Among other considerations, children should be old enough to understand basic facts about the clinical trial in order to provide assent to participate.

In the informed consent process, what are important considerations to take into account in cases when the potential participant is a child? For example, how should the informed consent clearly communicate to the patient the potential benefits and risks of a study?

B. Meeting Attendance and Participation

If you wish to attend this meeting, visit *http://iempatientfocused.eventbrite.com*. Please register by May 27, 2014. Those who are unable to attend the meeting in person can register to view a live Webcast of the meeting. You will be asked to indicate in your registration if you plan to attend in person or via the Webcast. Your registration will also contain your complete contact information, including name, title, affiliation, address, email address, and phone number. Seating will be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability. If you need special accommodations because of disability, please contact Pujita Vaidya (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

Patients who are interested in presenting comments as part of the initial panel discussions will be asked to indicate in their registration which topic(s) they wish to address. They will be asked to send a brief summary of responses to the topic questions to *PatientFocused@fda.hhs.gov*. Panelists will be notified of their selection a few days after the close of registration on May 27, 2014. FDA will try to accommodate all patients and patient advocate participants who wish to speak, either through the panel discussion or audience participation; however, the duration of comments may be limited by time constraints.

Comments: Regardless of attendance at the public meeting, you can submit electronic or written responses to the questions pertaining to topics 1 and 2 to the public docket (see **ADDRESSES**) by August 11, 2014. 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*.

Transcripts: As soon as a transcript is available, FDA will post it at *http://www.fda.gov/Drugs/NewsEvents/ucm387057.htm*.

Dated: April 22, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–09468 Filed 4–24–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Joint Meeting of the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management 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 Committees: Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee.

General Function of the Committees: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 16, 2014, from 8 a.m. to 5 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. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Yvette Waples, 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: *PDAC@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 committees will discuss the risk of serious neuropsychiatric adverse events with CHANTIX (varenicline tartrate) tablets, NDA 21928, Pfizer, Inc., and discuss options for addressing this risk.

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 1, 2014. 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 September 23, 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 September 24, 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 Yvette Waples 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: April 22, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–09460 Filed 4–23–14; 11:15 am]

BILLING CODE 4160–01–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, Maryland 20857; (301) 443–6593.

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 Section 2114 of the PHS Act or as set forth at 42 CFR 100.3, as applicable. This Table lists for each covered childhood vaccine the conditions which 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