

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

“[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 March 1, 2014, through March 31, 2014. 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) “Sustained, 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) “Sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine” referred to in the Table.

In accordance with Section 2112(b)(2), all interested persons may submit written information relevant to the issues described above in the case of the petitions listed below. Any person choosing to do so should file an original and three (3) copies of the information with the Clerk of the U.S. Court of Federal Claims at the address listed above (under the heading **FOR FURTHER INFORMATION CONTACT**), with a copy to HRSA addressed to Director, Division of Vaccine Injury Compensation Program, Healthcare Systems Bureau, 5600 Fishers Lane, Room 11C-26, Rockville, MD 20857. The Court’s caption (Petitioner’s Name v. Secretary of Health and Human Services) and the docket number assigned to the petition should be used as the caption for the written submission. Chapter 35 of title 44, United States Code, related to paperwork reduction, does not apply to information required for purposes of carrying out the Program.

Dated: April 19, 2014.

Mary K. Wakefield,
Administrator.

List of Petitions Filed

1. Dawn Somelofski on behalf of A.S., Albany, New York, Court of Federal Claims No: 14–0169V
2. Mikayla Rose Burchill, St. Charles, Illinois, Court of Federal Claims No: 14–0176V
3. Matthew Andrews, Cincinnati, Ohio, Court of Federal Claims No: 14–0181V
4. Thomas and Ashley Saunders on behalf of T.A.S., Evans, Georgia, Court of Federal Claims No: 14–0184V
5. Michelle Schneider, Washington District of Columbia, DC, Court of Federal Claims No: 14–0185V
6. Jana Wilkes on behalf of D.N.T., Fort Worth, Texas, Court of Federal Claims No: 14–0186V
7. Itza Mejia on behalf of Brenda Mejia, Deceased, Downey, California, Court of Federal Claims No: 14–0189V
8. Andy De’ on behalf of Annapoorna “Uma” De’, Irving, Texas, Court of Federal Claims No: 14–0190V
9. Kyle and Shannon Carda on behalf of G.J.C., Sioux Falls, South Dakota, Court of Federal Claims No: 14–0191V
10. Bruce McDonald, Riverdale, Georgia, Court of Federal Claims No: 14–0192V
11. Miranda Hoffman, Tuscaloosa, Alabama, Court of Federal Claims No: 14–0195V
12. Marie Verdier, Georgetown, Delaware, Court of Federal Claims No: 14–0196V
13. Martin D. Casper, San Diego, California, Court of Federal Claims No: 14–0197V
14. Stephen Wallen, Colorado Springs, Colorado, Court of Federal Claims No: 14–0209V
15. Alex Joiner, Guy C. Joiner, Dwain Joiner, Dorothy Jean Disher, Linda Guagliardo, and Robbin Thompson, on behalf of Henrietta Duplessis Joiner, Deceased, New Orleans, Louisiana, Court of Federal Claims No: 14–0211V
16. Caylee Harrington, Tempe, Arizona, Court of Federal Claims No: 14–0212V
17. Melodie Rose on behalf of Allison Rose, Mountain View, California, Court of Federal Claims No: 14–0215V
18. Damien Dufour, Lewiston, Maine, Court of Federal Claims No: 14–0219V
19. Michael Foy, Mayfield, Kentucky, Court of Federal Claims No: 14–0220V
20. Cynthia Winward on behalf of James Winward, Yuba City, California, Court of Federal Claims No: 14–0223V
21. Paul Drobbin, West Long Branch, New Jersey, Court of Federal Claims No: 14–0225V
22. Bridget Sullivan on behalf of James Sullivan, Granard, County Longford, Ireland, Court of Federal Claims No: 14–0226V
23. Krystyn Snyder, Pittsburgh, Pennsylvania, Court of Federal Claims No: 14–0227V
24. Janice D. Whitfield, Kentwood, Michigan, Court of Federal Claims No: 14–0231V
25. Lisa Brown and Christopher Brown on behalf of Z.B., Torrington, Connecticut, Court of Federal Claims No: 14–0234V
26. Victoria Nifakos, Loxahatchee, Florida, Court of Federal Claims No: 14–0236V
27. Linda Leggett, Hattiesburg, Mississippi, Court of Federal Claims No: 14–0238V
28. James Schutte on behalf of Carolyn Schutte, Excelsior Springs, Missouri, Court of Federal Claims No: 14–0239V
29. Carey Sweet, Sacramento, California, Court of Federal Claims No: 14–0240V
30. Brian Lauer, Boston, Massachusetts, Court of Federal Claims No: 14–0244V
31. Joaquim Pereira, Boston, Massachusetts, Court of Federal Claims No: 14–0246V
32. Michael Askew, Durham, North Carolina, Court of Federal Claims No: 14–0252V
33. Charmaine Johnson on behalf of K.J., Houston, Texas, Court of Federal Claims No: 14–0254V

[FR Doc. 2014–09422 Filed 4–24–14; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request, Questionnaire Cognitive Interviewing and Pretesting (NCI)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in