

appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

*Agenda:* During the morning session, the committee will discuss cognitive dysfunction in major depressive disorder (MDD). This is an evolving concept and experts in the field have not yet reached consensus as to whether cognitive dysfunction in MDD is a distinct entity. The committee will consider the clinical presentation of cognitive dysfunction in MDD, as well as methods for assessing this condition.

During the afternoon session, the committee will discuss new drug application 204447/supplemental new drug application 006, on the effectiveness of vortioxetine for the treatment of cognitive dysfunction in MDD, submitted by Takeda Development Center Americas, Inc.

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 January 20, 2016. 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 January 11, 2016. 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 January 12, 2016.

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 Kalyani Bhatt 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: November 23, 2015.

**Jill Hartzler Warner,**

*Associate Commissioner for Special Medical Programs.*

[FR Doc. 2015-30296 Filed 11-27-15; 8:45 am]

**BILLING CODE 4164-01-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, 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 October 1, 2015, through October 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, 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 Injury Compensation Programs, 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: November 19, 2015.

**James Macrae,**

*Acting Administrator.*

#### List of Petitions Filed

1. Maria Crespo on behalf of N. S., Cooper City, Florida, Court of Federal Claims No: 15–1100V
2. Loraine Herod, Cleveland, Ohio, Court of Federal Claims No: 15–1101V
3. Linda Gusky, Mt. Pleasant, Pennsylvania, Court of Federal Claims No: 15–1102V
4. David Helton, McKinney, Texas, Court of Federal Claims No: 15–1105V
5. Joanne Falk, Gaithersburg, Maryland, Court of Federal Claims No: 15–1106V
6. Karen Jehlen, Sussex, New Jersey, Court of Federal Claims No: 15–1107V
7. Galen L. Strong, Charlottesville, Virginia, Court of Federal Claims No: 15–1108V
8. Dennis Vivians, Chicago, Illinois, Court of Federal Claims No: 15–1111V
9. Dorothy Handel, Sterling, Illinois, Court of Federal Claims No: 15–1112V
10. Glenda Neher, Oklahoma City, Oklahoma, Court of Federal Claims No: 15–1114V
11. James A. Gustafson, El Jebel, Colorado, Court of Federal Claims No: 15–1115V
12. Jeanette Phillips, Boston, Massachusetts, Court of Federal Claims No: 15–1118V
13. Conception Plevak, Milwaukee, Wisconsin, Court of Federal Claims No: 15–1119V
14. Rachal P. LaPrairie, Alexandria, Louisiana, Court of Federal Claims No: 15–1120V
15. Seth Burk, Danville, Pennsylvania, Court of Federal Claims No: 15–1123V
16. Ashley House, Jacksonville, Florida, Court of Federal Claims No: 15–1124V
17. Ellyson Ostrovsky, Beachwood, Ohio, Court of Federal Claims No: 15–1125V
18. Thomas Simkiss, Newtown, Pennsylvania, Court of Federal Claims No: 15–1127V
19. Kathleen Heyer, Cedar Rapids, Iowa, Court of Federal Claims No: 15–1128V
20. Jamie Saracino, Dade City, Florida, Court of Federal Claims No: 15–1129V
21. James Woodward, Baltimore, Maryland, Court of Federal Claims No: 15–1130V
22. Susanne Whirley, Baxter, Minnesota, Court of Federal Claims No: 15–1131V
23. Denise Guzman, Whittier, California, Court of Federal Claims No: 15–1133V
24. Marvin Bradley Knight, Springfield, Missouri, Court of Federal Claims No: 15–1134V
25. Robert Leonard, Napa, California, Court of Federal Claims No: 15–1135V
26. Andrew Elefant, Lafayette, California, Court of Federal Claims No: 15–1136V
27. Pitey Morgan, Boston, Massachusetts, Court of Federal Claims No: 15–1137V
28. Janice DeWall, St. Louis Park, Minnesota, Court of Federal Claims No: 15–1138V
29. Ana Tan, Humble, Texas, Court of Federal Claims No: 15–1141V
30. Ashok Patel, Alexandria, California, Court of Federal Claims No: 15–1143V
31. Lacy Miron on behalf of M. M., Eugene, Oregon, Court of Federal Claims No: 15–1144V
32. Jessica Reape, Fort Drum, New York, Court of Federal Claims No: 15–1146V
33. Sharon Nathans, Encinitas, California, Court of Federal Claims No: 15–1147V
34. Alyce Schwenn, Milwaukee, Wisconsin, Court of Federal Claims No: 15–1148V
35. John Scannell, Oak Lawn, Illinois, Court of Federal Claims No: 15–1149V
36. Albert Arias, Orange, Connecticut, Court of Federal Claims No: 15–1150V
37. Mazie Lawson, Versailles, Kentucky, Court of Federal Claims No: 15–1152V
38. Juana Olga Durand on behalf of Jorge Antonio Durand, Deceased, Hollywood, Florida, Court of Federal Claims No: 15–1153V
39. Maurice Hoss, Meridian, Idaho, Court of Federal Claims No: 15–1154V
40. Debra Daniels, Newport Beach, California, Court of Federal Claims No: 15–1155V
41. Allison Villafane, Stoney Brook, New York, Court of Federal Claims No: 15–1156V
42. Lisa Stuffle, Boston, Massachusetts, Court of Federal Claims No: 15–1159V
43. Robert Boyer, Boston, Massachusetts, Court of Federal Claims No: 15–1160V
44. Christina Coffey and James Coffey on behalf of E. C., Lakeland, Florida, Court of Federal Claims No: 15–1161V
45. Dione Mitchell, Brandon, Florida, Court of Federal Claims No: 15–1162V
46. David Powell, Seneca, South Carolina, Court of Federal Claims No: 15–1164V
47. Kathryn S. Leffler, Elgin, Illinois, Court of Federal Claims No: 15–1165V
48. Richard C. Zug and Laura C. Zug on behalf of T. E. Z., Raleigh, North Carolina, Court of Federal Claims No: 15–1166V
49. Ramona Knorr, Knoxville, Tennessee, Court of Federal Claims No: 15–1169V

50. Audrey M. Abbott, Elgin, Illinois, Court of Federal Claims No: 15-1170V
51. Carol A. Marsyla, Stillwater, Minnesota, Court of Federal Claims No: 15-1172V
52. Maheshchhan Inamdar, Wellesley Hills, Massachusetts, Court of Federal Claims No: 15-1173V
53. Colt Sanders, Dallas, Texas, Court of Federal Claims No: 15-1174V
54. Jeffrey Jarvis and Jessica Tomei on behalf of S. C. G. J., Berkeley, California, Court of Federal Claims No: 15-1176V
55. Marlene M. Nottage, Lakewood, Ohio, Court of Federal Claims No: 15-1177V
56. Joni Marco, El Cajon, California, Court of Federal Claims No: 15-1178V
57. Mary Radhakrishnan, Orange Park, Florida, Court of Federal Claims No: 15-1179V
58. Cinthia Van Alst on behalf of J. V., Phoenix, Arizona, Court of Federal Claims No: 15-1180V
59. Diane Odean Patrick, Scottsdale, Arizona, Court of Federal Claims No: 15-1181V
60. Joseph Grimaudo, Odessa, Florida, Court of Federal Claims No: 15-1182V
61. Ronny Dean Linebarger, Fort Worth, Texas, Court of Federal Claims No: 15-1185V
62. Mandy Bangerter on behalf of D. B., Cheyenne, Wyoming, Court of Federal Claims No: 15-1186V
63. Roosevelt Harper, Boston, Massachusetts, Court of Federal Claims No: 15-1188V
64. Alicia Lusk, Jacksonville, Florida, Court of Federal Claims No: 15-1190V
65. Victoria Thompson, La Plata, Maryland, Court of Federal Claims No: 15-1192V
66. Huest Swilley, Pensacola, Florida, Court of Federal Claims No: 15-1193V
67. William Smith, Middleburg Heights, Ohio, Court of Federal Claims No: 15-1194V
68. Deborah Bohm, Grovetown, Georgia, Court of Federal Claims No: 15-1195V
69. Justin Diaz on behalf of D. J. D., Panama City, Florida, Court of Federal Claims No: 15-1196V
70. Mark Thomann, Chicago, Illinois, Court of Federal Claims No: 15-1199V
71. Gary Willingham, Houston, Texas, Court of Federal Claims No: 15-1204V
72. Shirley Epps, Trappe, Pennsylvania, Court of Federal Claims No: 15-1205V
73. Kelly Tavano, Boston, Massachusetts, Court of Federal Claims No: 15-1206V
74. Roxanna Sarver, Littleton, New Hampshire, Court of Federal Claims No: 15-1207V
75. Sondra Ritchie-Coppler, Visalia, California, Court of Federal Claims No: 15-1208V
76. Erin Martinelli, Galt, California, Court of Federal Claims No: 15-1209V
77. Diann Alexander, Lebanon, Ohio, Court of Federal Claims No: 15-1211V
78. Adam Jack Kinder, Fort Benning, Georgia, Court of Federal Claims No: 15-1212V
79. Tadek Towpik and Renata Towpik on behalf of A. T., Chicago, Illinois, Court of Federal Claims No: 15-1213V
80. Kelly michelle Izell, Chattanooga, Tennessee, Court of Federal Claims No: 15-1214V
81. Christina Marshall, Forest Hill, Maryland, Court of Federal Claims No: 15-1215V
82. Jerome Unick, Wethersfield, Connecticut, Court of Federal Claims No: 15-1216V
83. John Rajotte, Washington, District of Columbia, Court of Federal Claims No: 15-1218V
84. Lindsey Johnsen, Baraboo, Wisconsin, Court of Federal Claims No: 15-1219V
85. Troy Sweatt and Brittany Sweatt on behalf of E. S., Dyersburg, Tennessee, Court of Federal Claims No: 15-1222V
86. Jessica Williams on behalf of E. W. H., Cheyenne, Wyoming, Court of Federal Claims No: 15-1224V
87. Debra Kelly, Hampstead, North Carolina, Court of Federal Claims No: 15-1225V
88. Connie M. Johns, Philipsburg, Pennsylvania, Court of Federal Claims No: 15-1226V
89. Lea Lydon, Lakeland, Florida, Court of Federal Claims No: 15-1227V
90. Diane Riddle, Bend, Oregon, Court of Federal Claims No: 15-1228V
91. Cynthia Bassett, Dallas, Georgia, Court of Federal Claims No: 15-1231V
92. Nancy Meramo on behalf of Glenn Meramo, Deceased, Vienna, Virginia, Court of Federal Claims No: 15-1234V
93. Barbara Stanley, Woodland Hills, California, Court of Federal Claims No: 15-1235V
94. Cathy Wesloskie, Baden, Pennsylvania, Court of Federal Claims No: 15-1237V
95. Paul R. Rodgers, Memphis, Tennessee, Court of Federal Claims No: 15-1238V
96. Jessica Jones, Vienna, Virginia, Court of Federal Claims No: 15-1239V
97. Kathleen Killea, Staten Island, New York, Court of Federal Claims No: 15-1240V
98. James Young, Chicago, Illinois, Court of Federal Claims No: 15-1241V
99. Kalli Kline, Ketchikan, Alaska, Court of Federal Claims No: 15-1243V
100. Steven Totten, Terre Haute, Indiana, Court of Federal Claims No: 15-1246V
101. Heather Chapell on behalf of G. R. C., Lithia, Florida, Court of Federal Claims No: 15-1247V
102. Bertha Hixson, Hixson, Tennessee, Court of Federal Claims No: 15-1248V
103. Bruce Miller, Highlands Ranch, Colorado, Court of Federal Claims No: 15-1251V
104. Stacey Spossey, Mooresville, North Carolina, Court of Federal Claims No: 15-1254V
105. Louai Salim, Phoenix, Arizona, Court of Federal Claims No: 15-1255V
106. Linda St. George, Kennewick, Washington, Court of Federal Claims No: 15-1257V
107. Taylor Lee Reynolds, Reno, Nevada, Court of Federal Claims No: 15-1258V
108. James D. Ellis, Firestone, Colorado, Court of Federal Claims No: 15-1259V
109. Deborah Kaiser, Pleasant Prairie, Wisconsin, Court of Federal Claims No: 15-1261V
110. Sirna Kyles, Las Vegas, Nevada, Court of Federal Claims No: 15-1262V
111. Linda K. Schupp, Tonawanda, New York, Court of Federal Claims No: 15-1264V
112. Kathleen Romero, Bridgewater, Massachusetts, Court of Federal Claims No: 15-1265V
113. Michael Crist, Phoenix, Arizona, Court of Federal Claims No: 15-1267V
114. Frederick J. Kruger, D.P.M., Fresno, California, Court of Federal Claims No: 15-1270V
115. Ricardo Gascon, Honolulu, Hawaii, Court of Federal Claims No: 15-1272V
116. Helene Quintana, Boston, Massachusetts, Court of Federal Claims No: 15-1273V
117. Estate of Cindy Bernardini, Rochester, New York, Court of Federal Claims No: 15-1274V
118. Janice Elliot, Hampton, Virginia, Court of Federal Claims No: 15-1276V
119. Kathy Jo Neverve, Kansas City, Missouri, Court of Federal Claims No: 15-1277V

- 120. Debra Allen, Wellesley Hills, Massachusetts, Court of Federal Claims No: 15-1278V
- 121. Paul McKenzie, Beverly Hills, California, Court of Federal Claims No: 15-1280V
- 122. Toni Boom, Dresher, Pennsylvania, Court of Federal Claims No: 15-1282V
- 123. Anna Hitt, Vienna, Virginia, Court of Federal Claims No: 15-1283V
- 124. Bonita Reeves, Vienna, Virginia, Court of Federal Claims No: 15-1284V
- 125. Alfred Altmiller, Denton, Texas, Court of Federal Claims No: 15-1285V
- 126. Carla Grivna on behalf of M G, Beverly Hills, California, Court of Federal Claims No: 15-1286V
- 127. Mary Clare Smith on behalf of C L S, Ormond Beach, Florida, Court of Federal Claims No: 15-1287V
- 128. Tressa J. Nelson, New London, Wisconsin, Court of Federal Claims No: 15-1288V
- 129. Alfred Anderson, Neptune, New Jersey, Court of Federal Claims No: 15-1289V
- 130. Susan Cottingham on behalf of K C, Phoenix, Arizona, Court of Federal Claims No: 15-1291V
- 131. Jennifer Soghomonian on behalf of K S, Lakewood, California, Court of Federal Claims No: 15-1292V
- 132. Ana Yuricek on behalf of Jeremy Yuricek, New York, New York, Court of Federal Claims No: 15-1293V
- 133. Lisa Santoroski, New York, New York, Court of Federal Claims No: 15-1294V

[FR Doc. 2015-30259 Filed 11-27-15; 8:45 am]

BILLING CODE 4165-15-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Office of the Secretary**

[Document Identifier: HHS-OS-0990-0302-30D]

**Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request**

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for revision of the approved information collection assigned OMB control number 0990-0302, scheduled to expire on December 31, 2015. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public on this ICR during the review and approval period.

**DATES:** Comments on the ICR must be received on or before December 30, 2015.

**ADDRESSES:** Submit your comments to *OIRA\_submission@omb.eop.gov* or via facsimile to (202) 395-5806.

**FOR FURTHER INFORMATION CONTACT:** Information Collection Clearance staff, *Information.CollectionClearance@hhs.gov* or (202) 690-6162.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting

information, please include the OMB control number 0990-0302-30D for reference. *Proposed Project:* Medical Reserve Corps Unit Profile and Reports (Revision)-OMB No. 0990-0302-Office of the Secretary/Office of the Assistant Secretary for Health/Office of the Surgeon General/Division of Civilian Volunteer Medical Reserve Corps (OS/OASH/OSG/DCVMRC) is changed to Office of the Secretary/Office of the Assistant Secretary for Preparedness and Response/Office of Emergency Management/Division of the Civilian Volunteer Medical Reserve Corps. This reorganization was effective as of 26 November 2014 as published in the **Federal Register** [FR Doc. 2014-28030 Filed 11-25-14; 8:45am].

*Abstract:* Medical Reserve Corps units are currently located in almost 1,000 communities across the United States, and represent a resource of more than 205,000 volunteers. In order to continue supporting the MRC units in communities across the United States, and to continue planning for future emergencies that are national in scope, detailed information about the MRC units, including unit demographics, contact information (regular and emergency), volunteer numbers, and information about activities is needed by the Division of Civilian Volunteer Medical Reserve Corps (DCVMRC). MRC Unit Leaders are asked to update this information on the MRC Web site at least quarterly, and to participate in a Technical Assistance Assessment at least annually. The MRC unit data collected has expanded to include a self-assessment tool for use by unit leaders to aid in developing their MRC unit. This OMB revision request is for 3 years.

**ESTIMATED ANNUALIZED BURDEN TABLE**

Collection tool	Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Unit Profile .....	MRC Unit Leader .....	1,000	4	30/60	2,000
TA Assessment .....	MRC Unit Leader .....	1,000	1	1	1,000
Factors for Success .....	MRC Unit Leader .....	1,000	4	30/60	2,000
Unit Activity Reporting .....	MRC Unit Leader .....	1,000	4	15/60	1,000
<b>Total .....</b>	.....	.....	.....	.....	<b>6,000</b>

**Terry S. Clark,**

*Office of the Secretary, Asst Paperwork Reduction Act Reports Clearance Officer.*

[FR Doc. 2015-30272 Filed 11-27-15; 8:45 am]

BILLING CODE 4150-47-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Meeting of the Presidential Advisory Council on HIV/AIDS**

**AGENCY:** Office of the Assistant Secretary for Health, Office of the

Secretary, Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Service (DHHS) is hereby giving notice that the Presidential Advisory Council