

3. *The date the application was approved:* April 15, 2015. FDA has verified the applicant's claim that NDA 206143 was approved on April 15, 2015.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 292 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <https://www.regulations.gov> at Docket Nos. FDA-2013-S-0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: January 26, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-01979 Filed 1-31-18; 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 (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HRSA is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the program), as required by the Public Health Service (PHS) Act, as amended. While the Secretary of HHS (the Secretary) 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 Lisa L. Reyes, Acting 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 08N146B, Rockville, MD 20857; (301) 443-6593, or visit our website 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 HHS, 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 December 1, 2017, through December 31, 2017. 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, 08N146B, Rockville, MD 20857. The Court's caption (*Petitioner's Name v. Secretary of HHS*) 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: January 26, 2018.

George Sigounas,
Administrator.

List of Petitions Filed

1. Janece Dix, Gibsonton, Florida, Court of Federal Claims No: 17-1859V
2. Constance Crabtree, Portland, Oregon, Court of Federal Claims No: 17-1860V
3. Norval Nichols, Washington, District of Columbia, Court of Federal Claims No: 17-1861V
4. Rachelle Gucwa on behalf of B. C., Tavernier, Florida, Court of Federal Claims No: 17-1862V
5. Sharla Bafia, Washington, District of Columbia, Court of Federal Claims No: 17-1863V
6. Gary Koslica, Kenosha, Wisconsin, Court of Federal Claims No: 17-1864V
7. Tiffany Twofoot, Nashua, New Hampshire, Court of Federal Claims No: 17-1866V
8. Lauren Wilkins, Pleasant Grove, Utah, Court of Federal Claims No: 17-1867V
9. Stephanie Fiorello and Anthony Fiorello on behalf of R. F., Westfield, New Jersey, Court of Federal Claims No: 17-1869V
10. Sara Zutter, Brooklyn, New York, Court of Federal Claims No: 17-1872V
11. Bailey McCammon, Avon, Indiana, Court of Federal Claims No: 17-1873V
12. Kristoff Hendrickson, Saint Louis Park, Minnesota, Court of Federal Claims No: 17-1878V
13. Andrew Sanchez-Aldana and Karina Sanchez-Aldana on behalf of V. S. A., San Diego, California, Court of Federal Claims No: 17-1879V
14. Kathy Biser, Streetsboro, Ohio, Court of Federal Claims No: 17-1880V
15. Tarmesha Brown, Phoenix, Arizona, Court of Federal Claims No: 17-1884V
16. Alma Rivera, New York, New York, Court of Federal Claims No: 17-1887V
17. Charles Presley, Cherry Log, Georgia, Court of Federal Claims No: 17-1888V
18. Kathleen M. Lesley, O'Fallon, Missouri, Court of Federal Claims No: 17-1889V
19. Lorrie Jones, D'Iberville, Mississippi, Court of Federal Claims No: 17-1890V
20. Annette Quintana, Montrose, Colorado, Court of Federal Claims No: 17-1891V
21. Keri Anne Bordelon, Hot Springs, Arkansas, Court of Federal Claims No: 17-1892V
22. Janice Romano, Glassboro, New Jersey, Court of Federal Claims No: 17-1893V
23. Elizabeth Watkins, Washington, District of Columbia, Court of Federal Claims No: 17-1894V
24. Gayle Lawless Cox, Los Gatos, California, Court of Federal Claims No: 17-1895V
25. Valerie Newport, Phoenix, Arizona, Court of Federal Claims No: 17-1897V
26. Carla Durham, Pitcairn, Pennsylvania, Court of Federal Claims No: 17-1899V
27. Carol Gutierrez, Des Moines, Iowa, Court of Federal Claims No: 17-1904V
28. Joan Forrest, Holladay, Utah, Court of Federal Claims No: 17-1905V
29. Jeanne Rafferty, Washington, District of Columbia, Court of Federal Claims No: 17-1906V
30. Traci Wilks Jones, High Point, North Carolina, Court of Federal Claims No: 17-1907V
31. Robin Wynne, Boston, Massachusetts, Court of Federal Claims No: 17-1908V
32. Emily Middleton, Mt. Sterling, Kentucky, Court of Federal Claims No: 17-1910V
33. Willie J. Blackmon, Banning, California, Court of Federal Claims No: 17-1911V
34. Reva Sims, Missoula, Montana, Court of Federal Claims No: 17-1913V
35. Darlene Howe, Encinitas, California, Court of Federal Claims No: 17-1914V
36. Angela Apuzzo, Boston, Massachusetts, Court of Federal Claims No: 17-1915V
37. Jonathan Rogan on behalf of T. R., Encinitas, California, Court of Federal Claims No: 17-1916V
38. Sheri Grove, Cedartown, Georgia, Court of Federal Claims No: 17-1917V
39. Douglas Kelly, Rockville, Maryland, Court of Federal Claims No: 17-1918V
40. Tracy McCormick, Lombard, Illinois, Court of Federal Claims No: 17-1919V
41. Goret Parsloe, Washington, District of Columbia, Court of Federal Claims No: 17-1920V
42. Robert Lermond, Washington, District of Columbia, Court of Federal Claims No: 17-1921V
43. Steven S. Mills on behalf of Meri E. Boatman, Washington, District of Columbia, Court of Federal Claims No: 17-1922V
44. Sandra Williams, Bemidji, Minnesota, Court of Federal Claims No: 17-1925V
45. Amanda Tripp, Lewiston, Maine, Court of Federal Claims No: 17-1926V
46. Kimberly Smyth, Washington, District of Columbia, Court of Federal Claims No: 17-1927V
47. Charyl Wojtaszek, Washington, District of Columbia, Court of Federal Claims No: 17-1928V
48. Katherine J. Rader, Maple Grove, Minnesota, Court of Federal Claims No: 17-1929V
49. Bradford Kaup, Boise, Idaho, Court of Federal Claims No: 17-1930V
50. Deanna Drayton, New York, New York, Court of Federal Claims No: 17-1932V
51. Echo Llewellyn, Washington, District of Columbia, Court of Federal Claims No: 17-1934V
52. James Phillips, Washington, District of Columbia, Court of Federal Claims No: 17-1935V
53. Melody Chesley, Homer, Alaska, Court of Federal Claims No: 17-1936V
54. Cynthia Alexander, Washington, District of Columbia, Court of Federal Claims No: 17-1939V
55. Tracy Oehling, Manassas Park, Virginia, Court of Federal Claims No: 17-1940V
56. Derhyl Middleton, Washington, District of Columbia, Court of Federal Claims No: 17-1942V
57. Opal Waltz, Front Royal, Virginia, Court of Federal Claims No: 17-1943V
58. Judith Mora, Chandler, Arizona, Court of Federal Claims No: 17-1945V
59. Rebecca Crane and Grant Crane on behalf of S. C., Tucson, Arizona, Court of Federal Claims No: 17-1947V
60. Christine Rayner, Cranston, Rhode Island, Court of Federal Claims No: 17-1953V
61. Michael Valse, Toms River, New Jersey, Court of Federal Claims No: 17-1956V
62. Luciana Chaves and Rodrigo Calloni on behalf of A. C., Wheaton, Maryland, Court of Federal Claims No: 17-1957V
63. Mara Corter, Raleigh, North Carolina, Court of Federal Claims No: 17-1961V
64. Penny Cornelius, Port Huron, Michigan, Court of Federal Claims No: 17-1963V
65. Alexandra Morrow, Port Huron, California, Court of Federal Claims No: 17-1964V
66. Joseph Hilo, Lititz, Pennsylvania, Court of Federal Claims No: 17-1965V
67. Darrell Lamont Tatum, Wellesley Hills, Massachusetts, Court of Federal Claims No: 17-1966V
68. Chandra Novak, Howell, Michigan, Court of Federal Claims No: 17-1967V
69. Genarina Decastro, Philadelphia, Pennsylvania, Court of Federal Claims No: 17-1973V
70. Jeana Milton on behalf of Thirza Arlene Bagley, Deceased, Standale, Michigan, Court of Federal Claims No: 17-1974V
71. Katherine Duke, Amarillo, Texas, Court of Federal Claims No: 17-1976V
72. Kenneth Cuevas, Durham, North Carolina, Court of Federal Claims No: 17-1978V
73. Jackie Duty, Dallas, Texas, Court of Federal Claims No: 17-1979V
74. Rhoda Cohen, Howard Beach, New York, Court of Federal Claims No: 17-1980V
75. Angela Avanti, Washington, District of Columbia, Court of Federal Claims No: 17-1986V
76. Faith Hoelzel, Mukwonago, Wisconsin, Court of Federal Claims No: 17-1987V
77. Andrew Bartosiewicz and Lonya Bartosiewicz on behalf of J. B., Pittsburgh, Pennsylvania, Court of Federal Claims No: 17-1988V
78. Doreen Clouser, Marshall, Illinois, Court of Federal Claims No: 17-1989V
79. Janell Ross, Washington, District of Columbia, Court of Federal Claims No: 17-1992V
80. Ralph M. Pavelka, Mora, Minnesota, Court of Federal Claims No: 17-1993V
81. Ashley Crenshaw, Baltimore, Maryland, Court of Federal Claims No: 17-1994V
82. Heather Lynch, Boston, Massachusetts, Court of Federal Claims No: 17-1995V
83. Marylou Porzio, Washington, District of Columbia, Court of Federal Claims No: 17-1996V
84. Melvina Wong, Washington, District of Columbia, Court of Federal Claims No: 17-1997V
85. Angela Lynch, Washington, District of Columbia, Court of Federal Claims No: 17-1999V
86. Leslie Kraus, Bensalem, Pennsylvania, Court of Federal Claims No: 17-2001V
87. Ramona Dicom, Linwood, New Jersey, Court of Federal Claims No: 17-2002V
88. Martha Stanford, Florence, Alabama, Court of Federal Claims No: 17-2005V
89. Karen Hergett, Billings, Montana, Court of Federal Claims No: 17-2008V
90. Emily McHenry, Chicago, Illinois, Court of Federal Claims No: 17-2009V
91. George Foster, Henderson, New York, Court of Federal Claims No: 17-2010V
92. Laila Saghir, Owings Mills, Maryland,

- Court of Federal Claims No: 17–2011V
93. Michael Dore, Cambridge, Massachusetts, Court of Federal Claims No: 17–2012V
94. Crystal Hill, Philadelphia, Pennsylvania, Court of Federal Claims No: 17–2013V
95. Harry Wilmore, Philadelphia, Pennsylvania, Court of Federal Claims No: 17–2014V
96. Elizabeth Mozer, Dresher, Pennsylvania, Court of Federal Claims No: 17–2015V
97. Jacqueline Pohlman, Auburn, Washington, Court of Federal Claims No: 17–2016V
98. Randall Fennig, Vienna, Virginia, Court of Federal Claims No: 17–2019V
99. Sarah L. Neal and Richard C. Neal on behalf of C. N., Deceased, Ocean City, New Jersey, Court of Federal Claims No: 17–2020V
100. Sarah Neal, Ocean City, New Jersey, Court of Federal Claims No: 17–2021V
101. Stephanie Myers, Towson, Maryland, Court of Federal Claims No: 17–2025V
102. Danielle Gilmore, Bradenton, Florida, Court of Federal Claims No: 17–2026V
103. Marissa Bialek, Washington, District of Columbia, Court of Federal Claims No: 17–2030V
104. Maria Elmakky, Washington, District of Columbia, Court of Federal Claims No: 17–2032V
105. Hoang-Hoa Nguyen on behalf of Tuyet Mai, Wellesley Hills, Massachusetts, Court of Federal Claims No: 17–2051V
106. Angela Gornowicz, Cuyahoga Falls, Ohio, Court of Federal Claims No: 17–2053V
107. Lucinda Kelley, Atlanta, Georgia, Court of Federal Claims No: 17–2054V
108. Cheyenne Prescott, Englewood, New Jersey, Court of Federal Claims No: 17–2055V
109. Sylvia Wiseman, Indianapolis, Indiana, Court of Federal Claims No: 17–2060V
110. Brian Anklam and Karen Anklam on behalf of N. A., Twin Falls, Idaho, Court of Federal Claims No: 17–2061V
111. Dean Hrieche, Englewood, New Jersey, Court of Federal Claims No: 17–2063V

[FR Doc. 2018–02052 Filed 1–31–18; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute on Aging Special Emphasis Panel, February 16, 2018, 1:00 p.m. to February 16, 2018, 4:00 p.m., National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2W200, Bethesda, MD 20892 which was published in the **Federal Register** on January 11, 2018, 83 FR 1375.

The meeting notice is amended to change the date of the meeting from February 16, 2018 to February 15, 2018.

The location and time remain the same. The meeting is closed to the public.

Dated: January 29, 2018.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–02036 Filed 1–31–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, January 23, 2018, 1:00 p.m. to January 23, 2018, 5:00 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on January 03, 2018, 83 FR PG 387.

The meeting will be held on March 7, 2018 at 1:00 and end at 3:30. The meeting location remains the same. The meeting is closed to the public.

Dated: January 29, 2018.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–02032 Filed 1–31–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIH Research Project Grant (Parent R01).

Date: March 5, 2018.

Time: 1:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892, (Telephone Conference Call).

Contact Person: Dharmendar Rathore, Ph.D., Senior Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3G30, National Institutes of Health/NIAID, 5601 Fishers Lane, Drive, MSC 9823, Bethesda, MD 20892–9823, 240–669–5058, rathored@mail.nih.gov. (Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: January 29, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–02037 Filed 1–31–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Neuroscience of Aging Review Committee, February 1, 2018, 8:00 a.m. to February 2, 2018, 2:00 p.m., Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814 which was published in the **Federal Register** on January 3, 2018, 83 FR 386.

The meeting notice is amended to change the meeting location from Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814 to Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Rd., Rockville MD 20852. The meeting is closed to the public.

Dated: January 29, 2018.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–02035 Filed 1–31–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as