

FOR FURTHER INFORMATION CONTACT:

Caryn Cohen, Office of Science, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 1-877-287-1373, email: TPSAC@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 website at <https://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.

SUPPLEMENTARY INFORMATION:

Agenda: On February 6-7, 2019, the Committee will convene for two sessions. The first session will convene on February 6, 2019, during which the Committee will discuss an amendment to the modified risk tobacco product applications (MRTPAs), submitted by Swedish Match North America for the following snus smokeless tobacco products:

- MR0000020: General Loose;
- MR0000021: General Dry Mint Portion Original Mini;
- MR0000022: General Portion Original Large;
- MR0000024: General Classic Blend Portion White Large-12ct;
- MR0000025: General Mint Portion White Large;
- MR0000027: General Nordic Mint Portion White Large-12ct;
- MR0000028: General Portion White Large; and
- MR0000029: General Wintergreen Portion White Large.

The second session will convene, after the first session has concluded, on February 6, 2019, and continue on February 7, 2019. During the second session the Committee will discuss the MRTPA, submitted by Altria Client Services LLC on behalf of U.S. Smokeless Tobacco Company LLC for the following smokeless tobacco product:

- MR0000108: Copenhagen Snuff Fine Cut.

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 website 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 website after the meeting. Background material is available at <https://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 22, 2019. Oral presentations from the public for the first session will be scheduled between approximately 10 a.m. and 10:30 a.m. on February 6, 2019, and for the second session between approximately 8 a.m. and 8:30 a.m. on February 7, 2019. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement describing the general nature of the evidence or arguments they wish to present, the names and email addresses of proposed participants, and the session during which they would like to speak, on or before January 14, 2019. 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 15, 2019.

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 Caryn Cohen (see: **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm11462.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: December 4, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-26721 Filed 12-10-18; 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 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, Clerk of Court, 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 October 1, 2018, through October 31, 2018. 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: November 30, 2018.

George Sigounas,
Administrator.

List of Petitions Filed

- Diane Tobin, New London, Connecticut, Court of Federal Claims No: 18-1516V
2. John Homan, Peoria, Illinois, Court of Federal Claims No: 18-1517V
3. Sharon Borris, Tiffin, Ohio, Court of Federal Claims No: 18-1518V
4. Edward Boni, Pittsburgh, Pennsylvania, Court of Federal Claims No: 18-1519V
5. Erin M. Kinney, Linwood, New Jersey, Court of Federal Claims No: 18-1522V
6. Michael J. Periard, Ithaca, New York, Court of Federal Claims No: 18-1524V
7. Anne M. Alexander on behalf of Marilyn Osborne Rock, Deceased, Denver, Colorado, Court of Federal Claims No: 18-1525V
8. Thomas Bade, Pearl River, New York, Court of Federal Claims No: 18-1526V
9. Deana Knowles, Middle Granville, New York, Court of Federal Claims No: 18-1527V
10. Dionni De La Cruz, Houston, Texas, Court of Federal Claims No: 18-1528V
11. Anthony Sanders, Alexandria, Louisiana, Court of Federal Claims No: 18-1529V
12. Janice Y. Atencio, Espanola, New Mexico, Court of Federal Claims No: 18-1530V
13. Dawna Michelle Cox on behalf of David Carroll Cox, Deceased, Shelbyville, Kentucky, Court of Federal Claims No: 18-1531V
14. William C. Carter, Prospect Hill, North Carolina, Court of Federal Claims No: 18-1532V
15. Sarah Huff, St. Petersburg, Florida, Court of Federal Claims No: 18-1533V
16. Jamie Blaylock, Overland Park, Kansas, Court of Federal Claims No: 18-1534V
17. Kenneth A. Bradley, Naples, Maine, Court of Federal Claims No: 18-1535V
18. Joan Benz, Maryland Heights, Missouri, Court of Federal Claims No: 18-1536V
19. Kristen Iniguez on behalf of K. J. I., San Diego, California, Court of Federal Claims No: 18-1537V
20. Durenda Whitehead and Keynard Shawtell Johnson, Sr. on behalf of K. S.

- J. Jr., Macon, Georgia, Court of Federal Claims No: 18-1538V
21. LaDonna Foster, Willow Brook, Illinois, Court of Federal Claims No: 18-1540V
22. Annie Brown, White Plains, New York, Court of Federal Claims No: 18-1542V
23. Heather Massey, Salt Lake City, Utah, Court of Federal Claims No: 18-1543V
24. Rebeca A. Nolan, Saugerties, New York, Court of Federal Claims No: 18-1544V
25. Randy L. Taylor, Longview, Texas, Court of Federal Claims No: 18-1545V
26. Dorn Dytmer, Gwinn, Michigan, Court of Federal Claims No: 18-1546V
27. Paulette Falbo, Northport, New York, Court of Federal Claims No: 18-1547V
28. Robert Fulling, Chicago, Illinois, Court of Federal Claims No: 18-1549V
29. Elizabeth Valdez, San Mateo, California, Court of Federal Claims No: 18-1550V
30. Lori A. Hughes, Madison, Wisconsin, Court of Federal Claims No: 18-1554V
31. Jennifer Schlata, Pittsburgh, Pennsylvania, Court of Federal Claims No: 18-1557V
32. Natalia A. Augustine, Westmont, Illinois, Court of Federal Claims No: 18-1558V
33. Kathy Cummings Gillim, Farmington Hills, Michigan, Court of Federal Claims No: 18-1560V
34. Linda Wirtshafter, Woodmere, Ohio, Court of Federal Claims No: 18-1562V
35. Thomas A. Metzger, Newport, Washington, Court of Federal Claims No: 18-1565V
36. Pamela A. Stricker and Jerry Stricker on behalf of Pamela Stricker, Lima, Ohio, Court of Federal Claims No: 18-1569V
37. Kathleen Bartholomew, Park Forest, Illinois, Court of Federal Claims No: 18-1570V
38. Michael Lusk, Granite Bay, California, Court of Federal Claims No: 18-1571V
39. Lee Meagher, Danvers, Massachusetts, Court of Federal Claims No: 18-1572V
40. Debbie Buck, Murray, Utah, Court of Federal Claims No: 18-1573V
41. Georgie Fletcher, Brooklyn, New York, Court of Federal Claims No: 18-1574V
42. Paxton T. King, Middleton, Wisconsin, Court of Federal Claims No: 18-1575V
43. Raghu Duggirala, Philadelphia, Pennsylvania, Court of Federal Claims No: 18-1578V
44. Maryam Shahbazian, Santa Clara, California, Court of Federal Claims No: 18-1580V
45. Jennifer Durant, Boston, Massachusetts, Court of Federal Claims No: 18-1581V
46. Carol A. Allen, Easton, Massachusetts, Court of Federal Claims No: 18-1582V
47. Patrick Patterson, Lubbock, Texas, Court of Federal Claims No: 18-1583V
48. Daniel J. Petrie, Arcade, New York, Court of Federal Claims No: 18-1584V
49. Gertrude Smilo on behalf of Joseph G. Smilo, Deceased, Pittsburgh, Pennsylvania, Court of Federal Claims No: 18-1585V
50. Elizabeth Austin, Boston, Massachusetts, Court of Federal Claims No: 18-1587V
51. Michele Peterson, Webster Groves, Missouri, Court of Federal Claims No: 18-1589V
52. Scott Bowsher and Candy Bowsher on behalf of M. B., Rockville, Indiana, Court

- of Federal Claims No: 18–1590V
53. Lisa Sinko, Farmington Hills, Michigan, Court of Federal Claims No: 18–1592V
 54. Travis Reitter, Oakland, California, Court of Federal Claims No: 18–1593V
 55. Connie Tregle, Lake Charles, Louisiana, Court of Federal Claims No: 18–1596V
 56. Scott Skiles and Misty Skiles on behalf of M. S., Boston, Massachusetts, Court of Federal Claims No: 18–1597V
 57. Brenda L. Slay, Salina, Kansas, Court of Federal Claims No: 18–1598V
 58. Michele Bernardo, West Chester, Pennsylvania, Court of Federal Claims No: 18–1599V
 59. Lisa Whitehead-Williams, Chicago, Illinois, Court of Federal Claims No: 18–1600V
 60. Linda Chervenok, Paterson, New Jersey, Court of Federal Claims No: 18–1601V
 61. Andres Nieves, Novi, Michigan, Court of Federal Claims No: 18–1602V
 62. Jimmie L. Foster, Asheville, North Carolina, Court of Federal Claims No: 18–1605V
 63. Jesus Romo-Villanueva, Tucson, Arizona, Court of Federal Claims No: 18–1609V
 64. Frances Basler, Spokane Valley, Washington, Court of Federal Claims No: 18–1614V
 65. Richard Brieseacher, Mount Vernon, Illinois, Court of Federal Claims No: 18–1616V
 66. Deborah Ann Dunatov, Douglasville, Georgia, Court of Federal Claims No: 18–1617V
 67. Carol McCarvell, Austin, Texas, Court of Federal Claims No: 18–1618V
 68. Kelsey Rathjen, Littleton, Colorado, Court of Federal Claims No: 18–1619V
 69. Dawn Brooks, Millville, New Jersey, Court of Federal Claims No: 18–1620V
 70. Michele Nelson Ruppert, San Francisco, California, Court of Federal Claims No: 18–1621V
 71. Michael Francesco, Maiden, North Carolina, Court of Federal Claims No: 18–1622V
 72. Robert G. Canady and Sita S. Canady on behalf of A.G.C., Fredericksburg, Virginia, Court of Federal Claims No: 18–1624V
 73. Roy Romero, San Antonio, Texas, Court of Federal Claims No: 18–1625V
 74. William Lederer, Norwalk, Connecticut, Court of Federal Claims No: 18–1627V
 75. Allison Ferrini on behalf of W.F., Morton Grove, Illinois, Court of Federal Claims No: 18–1628V
 76. Patricia Moore on behalf of Dr. Timonthy Moore, Deceased, Phoenix, Arizona, Court of Federal Claims No: 18–1629V
 77. Glenda Lee Stewart, Chicago, Illinois, Court of Federal Claims No: 18–1630V
 78. Cheryl Kraemer, Madison Heights, Michigan, Court of Federal Claims No: 18–1631V
 79. Douglas F. Crawford, Panorama City, California, Court of Federal Claims No: 18–1632V
 80. William S. Boylston, McMinnville, Oregon, Court of Federal Claims No: 18–1634V
 81. Nancy Henderson, Myrtle Creek, Oregon, Court of Federal Claims No: 18–1635V
 82. Helen Marie Pell, Indianapolis, Indiana, Court of Federal Claims No: 18–1636V
 83. Virginia Powell, Dallas, Texas, Court of Federal Claims No: 18–1638V
 84. Kathleen Mitzner, Livingston, Montana, Court of Federal Claims No: 18–1639V
 85. Azusa Nash on behalf of U.C.N., Richmond, Virginia, Court of Federal Claims No: 18–1640V
 86. Christopher W. Lindbloom, Richmond, Virginia, Court of Federal Claims No: 18–1642V
 87. Francesca Ohanian, Foster City, California, Court of Federal Claims No: 18–1643V
 88. Rebecca Huffman, Fort Wayne, Indiana, Court of Federal Claims No: 18–1646V
 89. Brenda Rae Smith, Bethesda, Maryland, Court of Federal Claims No: 18–1648V
 90. Betty Jeter on behalf of Estate of Rexford N. Jeter, Deceased, Montgomery, Alabama, Court of Federal Claims No: 18–1649V
 91. Tina Walker, Fredericksburg, Pennsylvania, Court of Federal Claims No: 18–1650V
 92. Rosanne Ledet, Washington, District of Columbia, Court of Federal Claims No: 18–1651V
 93. Nancy Spotanski, Ballwin, Missouri, Court of Federal Claims No: 18–1653V
 94. Gareth Acton, Pittsburgh, Pennsylvania, Court of Federal Claims No: 18–1654V
 95. John R. Harnisch, Pleasant Prairie, Wisconsin, Court of Federal Claims No: 18–1656V
 96. Kristine Rucker-Morrow, Chicago, Illinois, Court of Federal Claims No: 18–1657V
 97. Cecilia Ruzzene, Knoxville, Tennessee, Court of Federal Claims No: 18–1658V
 98. Claudine Carter, South Euclid, Ohio, Court of Federal Claims No: 18–1659V
 99. Sheree Kaufman, Greensboro, North Carolina, Court of Federal Claims No: 18–1661V
 100. Angela Holt, Stafford, Virginia, Court of Federal Claims No: 18–1662V
 101. Anne Jacqueline Kite, Spotsylvania, Virginia, Court of Federal Claims No: 18–1663V
 102. Eric Larson, Columbia, Maryland, Court of Federal Claims No: 18–1666V
 103. Robert Tafuri, Marlborough, Massachusetts, Court of Federal Claims No: 18–1667V
 104. Dawn Halley, Cranbury, New Jersey, Court of Federal Claims No: 18–1668V
 105. Madeleine Soares, Dallas, Texas, Court of Federal Claims No: 18–1669V
 106. Karlee Tessmer, Pewaukee, Wisconsin, Court of Federal Claims No: 18–1672V
 107. Tonya Clark, Junction City, Kansas, Court of Federal Claims No: 18–1673V
 108. Martha Walker, Ocean City, New Jersey, Court of Federal Claims No: 18–1674V
 109. Deborah Flynn, Annapolis, Maryland, Court of Federal Claims No: 18–1675V
 110. Cecilia Nuss, St. Charles, Illinois, Court of Federal Claims No: 18–1676V
 111. Debra H. Childress, Midlothian, Virginia, Court of Federal Claims No: 18–1677V
 112. Tamra K. Craig, Westfield, Indiana, Court of Federal Claims No: 18–1678V
 113. Mary Finch, Chipley, Florida, Court of Federal Claims No: 18–1680V
 114. Joan Neptune, Franklin, Tennessee, Court of Federal Claims No: 18–1681V
 115. Lindsey Miller, Los Angeles, California, Court of Federal Claims No: 18–1682V
 116. April L. Strang-Kutay, Lancaster, Pennsylvania, Court of Federal Claims No: 18–1683V

[FR Doc. 2018–26760 Filed 12–10–18; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Nominations to the Advisory Committee on Blood and Tissue Safety and Availability

AGENCY: Office of HIV/AIDS and Infectious Disease Policy, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Office of Assistant Secretary for Health (OASH) is seeking nominations of qualified individuals to be considered for appointment as members of the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA). ACBTSA is a Federal advisory committee within the Department of Health and Human Services. Management support for the activities of this Committee is the responsibility of the OASH. The qualified individuals will be nominated to the Secretary of Health and Human Services for consideration of appointment as members of the ACBTSA. Members of the Committee, including the Chair, are appointed by the Secretary. Members are invited to serve on the Committee for up to four-year terms.

DATES: All nominations must be received no later than 4:00 p.m. ET on Friday, December 28 2018 at the address listed below.

ADDRESSES: All nominations should be sent to the ACBTSA email address at ACBTSA@hhs.gov. Alternatively, nominations can be mailed or delivered to: Mr. James Berger, Senior Advisor for Blood and Tissue Policy, Office of Assistant Secretary for Health, Department of Health and Human Services, 330 C Street SW, Room L001 Switzer Building, Washington, DC 20201. Telephone: (202) 795–7608; Email ACBTSA@hhs.gov.

FOR FURTHER INFORMATION CONTACT: Mr. James Berger, Senior Advisor for Blood and Tissue Policy. Contact information for Mr. Berger is provided above.

A copy of the Committee charter and roster of the current membership can be obtained by contacting Mr. Berger or by