

The reporting of manufacturing amount information under section 510(j)(3) of the FD&C Act is a new element to the information collection. We assume it takes 1 hour to prepare and submit the necessary reporting information and estimate an average of 22.5 reports will be submitted annually from 8,700 registrants. We exclude 1,780 respondents from the 10,480 registrants, (accounting for both biological product and drug product registrants) to reflect the reporting exemptions implemented under section 510(j)(3)(B). Also, based on informal communications, we have increased the estimate of burden we attribute to preparing and submitting the requisite information from 15 minutes to 1 hour.

Similarly, intending to ensure the availability of medically necessary drug products during emergencies that might result in high absenteeism at production facilities, we account for burden associated with the development of a manufacturing contingency plan as recommended in Agency guidance “Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products,” (March 2011), referenced above. We assume that most respondents have already developed a Plan as recommended by the guidance document as a usual and customary business practice, and limit therefore, our current burden estimate to updates, maintenance, and the reporting to FDA of the activation and deactivation of the Plan. We assume two notifications (for purposes of this analysis, we consider an activation and a deactivation notification to equal one notification) will be submitted to CDER annually, and estimate each notification requires an average of 16 hours to prepare and submit.

Finally, animal drug shortage information is also a new element to the information collection. Although not statutorily required, we estimate that 30 respondents will provide 2 notifications annually and that it will take 1 hour to prepare and submit each notification as recommended in the guidance document entitled “Reporting and Mitigating Animal Drug Shortages,” referenced above.

Cumulatively, these adjustments and modifications result in a decrease of 67,004 responses and an increase of 87,413 burden hours, annually. We have removed burden we attributed to developing and implementing electronic data systems as we now regard this activity as usual and customary, however we have increased our estimate of the time needed for some of the

activities to account for corresponding record maintenance.

Dated: December 16, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–30355 Filed 12–19–24; 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 8W–25A, Rockville, Maryland 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 United States Court of Federal Claims and to serve a copy of the petition to 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, 2024, through October 31, 2024. This list provides the name of the petitioner, city, and State of vaccination (if unknown then the city and State of the person or attorney filing the 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 United States 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, Health Systems Bureau, 5600 Fishers Lane, 8W-25A, Rockville, Maryland 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.

Diana Espinosa,

Principal Deputy Administrator.

List of Petitions Filed

1. Lynne Krispin, Deerwood, Minnesota, Court of Federal Claims No: 24-1546V
2. Julia Carabajal, Las Vegas, Nevada, Court of Federal Claims No: 24-1548V
3. Don Andrew Hampton, Sycamore, Illinois, Court of Federal Claims No: 24-1549V
4. Katelyn Crowley-Lum, Andover, Massachusetts, Court of Federal Claims No: 24-1551V
5. Althea Stevens, Morehead, Kentucky, Court of Federal Claims No: 24-1553V
6. Jose A. Inoa, Stormville, New York, Court of Federal Claims No: 24-1554V
7. Rachel Muzik, Avon, Ohio, Court of Federal Claims No: 24-1555V
8. Terry Ash, Price, Utah, Court of Federal Claims No: 24-1556V
9. Scott Pollina, Wheaton, Illinois, Court of Federal Claims No: 24-1557V
10. Carol Karmonick, Boston, Massachusetts, Court of Federal Claims No: 24-1559V
11. Carroll Williams, Dresher, Pennsylvania, Court of Federal Claims No: 24-1560V
12. Nicole Nickell on behalf of L.C., New Orleans, Louisiana, Court of Federal Claims No: 24-1562V
13. Valinda Torres, Boise, Idaho, Court of Federal Claims No: 24-1564V
14. Stephan P. Densby, Herald, California, Court of Federal Claims No: 24-1565V
15. Jesus Alvarado, Torrance, California, Court of Federal Claims No: 24-1566V
16. Nicole Primeau, Mukilteo, Washington, Court of Federal Claims No: 24-1568V
17. Julie Mertz, Algona, Iowa, Court of Federal Claims No: 24-1569V
18. Natasha Dorsey, Gaithersburg, Maryland, Court of Federal Claims No: 24-1570V
19. Taira Carrasquillo on behalf of L.M., Lisle, Illinois, Court of Federal Claims No: 24-1571V
20. Janet Murray on behalf of K.M., Los Angeles, California, Court of Federal Claims No: 24-1572V
21. Robert Berg, Lake Havasu City, Arizona, Court of Federal Claims No: 24-1573V
22. Steven J. Agnello, Kalamazoo, Michigan, Court of Federal Claims No: 24-1574V
23. Melissa Lagdameo, Dresher, Pennsylvania, Court of Federal Claims No: 24-1576V
24. Loretta Bates, Phoenix, Arizona, Court of Federal Claims No: 24-1578V
25. Brenda Lee Albers, Coldwater, Ohio, Court of Federal Claims No: 24-1579V
26. Shannon Vetere, Owings Mills, Maryland, Court of Federal Claims No: 24-1580V
27. Sarah Black, Grove City, Pennsylvania, Court of Federal Claims No: 24-1581V
28. Rachel Files Goulding, New York, New York, Court of Federal Claims No: 24-1582V
29. Keevia Porter, Horn Lake, Mississippi, Court of Federal Claims No: 24-1583V
30. Elizabeth Andrews-Pannone, Dresher, Pennsylvania, Court of Federal Claims No: 24-1584V
31. John Giammona, Encinitas, California, Court of Federal Claims No: 24-1586V
32. Susan Aguirre, Lakewood, California, Court of Federal Claims No: 24-1590V
33. Jamie Wong, New York, New York, Court of Federal Claims No: 24-1591V
34. Patty Pugh, Buckhannon, West Virginia, Court of Federal Claims No: 24-1592V
35. Sara Primus, Denver, Colorado, Court of Federal Claims No: 24-1593V
36. Marcel Walter Hingle, Newport, Arkansas, Court of Federal Claims No: 24-1594V
37. Rosa Byer, Camp Springs, Maryland, Court of Federal Claims No: 24-1595V
38. Nehemiah N. Nabors, Plymouth, Wisconsin, Court of Federal Claims No: 24-1598V
39. Alaeddine El Alayli, Boston, Massachusetts, Court of Federal Claims No: 24-1600V
40. Tamie Mancuso, DuBois, Pennsylvania, Court of Federal Claims No: 24-1601V
41. Cynthia Price, St. Louis, Missouri, Court of Federal Claims No: 24-1603V
42. Iretha Ross, Earle, Arkansas, Court of Federal Claims No: 24-1604V
43. Stuart Palmer, Joshua, Texas, Court of Federal Claims No: 24-1605V
44. Margarita Zamora Lujano on behalf of E. M., Deceased, Coalinga, California, Court of Federal Claims No: 24-1606V
45. Bettie Blackman, Boston, Massachusetts, Court of Federal Claims No: 24-1607V
46. Kelly Hawkins Skinner, Boston, Massachusetts, Court of Federal Claims No: 24-1609V
47. Miranda Starratt-Chobert, Milton, Florida, Court of Federal Claims No: 24-1610V
48. Daniel Thompson, Washington, District of Columbia, Court of Federal Claims No: 24-1615V
49. Raphael Golb, New York, New York, Court of Federal Claims No: 24-1616V
50. Stanley Bozaich, Atlanta, Georgia, Court of Federal Claims No: 24-1617V
51. Jerene Wickett, Omaha, Nebraska, Court of Federal Claims No: 24-1618V
52. Sarah Reynolds, Lexington, Kentucky, Court of Federal Claims No: 24-1619V
53. Steven Fink, Tampa, Florida, Court of Federal Claims No: 24-1620V
54. Robert Wright, Black River Falls, Wisconsin, Court of Federal Claims No: 24-1622V
55. Stefanie Topp, Charlotte, North Carolina, Court of Federal Claims No: 24-1623V
56. Holly Stair-Goshu, Houston, Texas, Court of Federal Claims No: 24-1625V
57. Cara Hayes, Boston, Massachusetts, Court of Federal Claims No: 24-1626V
58. Rebecca Androli, Buffalo, New York, Court of Federal Claims No: 24-1627V
59. Marisol Rivera, Belvidere, Illinois, Court of Federal Claims No: 24-1628V
60. Carol Wood, Matthews, North Carolina, Court of Federal Claims No: 24-1629V
61. Lisa Skirpan, Enola, Pennsylvania, Court of Federal Claims No: 24-1630V
62. Marta Pike, Wolcott, New York, Court of Federal Claims No: 24-1636V
63. Theresa Akers, Livingston, Texas, Court of Federal Claims No: 24-1637V
64. Lucia Lopez Guzman, Boston, Massachusetts, Court of Federal Claims No: 24-1638V
65. Kaitlyn Wawak on behalf of J.C., Bastrop, Texas, Court of Federal Claims No: 24-1639V
66. Nina Jarrad, Cary, North Carolina, Court of Federal Claims No: 24-1640V
67. Sandra L. Crowley, Cumberland, Rhode Island, Court of Federal Claims No: 24-1642V
68. Cheryl Campos, Littleton, Colorado, Court of Federal Claims No: 24-1643V
69. Jonathan Day, New York, New York, Court of Federal Claims No: 24-1644V
70. Cierra Shaver, Battle Ground, Washington, Court of Federal Claims No: 24-1647V
71. Charles L. Porter, Fox Lake, Wisconsin, Court of Federal Claims No: 24-1649V
72. Shivonne Anfield, Camden, New Jersey, Court of Federal Claims No: 24-1650V
73. Erika Verleye, Seattle, Washington, Court of Federal Claims No: 24-1651V
74. Douglas Bates, Richmond, Virginia, Court of Federal Claims No: 24-1652V
75. Sinisa Kolaric, Marietta, Georgia, Court of Federal Claims No: 24-1654V
76. Shemeka Turner, Dresher, Pennsylvania, Court of Federal Claims No: 24-1656V
77. Kendall Patterson, Tucson, Arizona, Court of Federal Claims No: 24-1657V
78. Kelly Zrimsek, Fitchburg, Massachusetts, Court of Federal Claims No: 24-1659V
79. Grace Reino, Boston, Massachusetts, Court of Federal Claims No: 24-1663V
80. Alexis Lyndon Early, Marysville, Ohio, Court of Federal Claims No: 24-1664V
81. June Augustine, Sykesville, Maryland, Court of Federal Claims No: 24-1667V
82. Jennifer Kazdan, Wallingford, Connecticut, Court of Federal Claims No: 24-1668V
83. Joanne Duitsman, Champaign, Illinois, Court of Federal Claims No: 24-1669V
84. Deborah Fish, Bridgewater Corners, Vermont, Court of Federal Claims No: 24-1670V
85. Linda Talbourdet, Boston, Massachusetts, Court of Federal Claims No: 24-1671V
86. Pa K. Lor, Johnston, Iowa, Court of Federal Claims No: 24-1672V
87. Sandra Bloomenthal, Boston, Massachusetts, Court of Federal Claims No: 24-1673V
88. Sandra Johnson, Dresher, Pennsylvania,

- Court of Federal Claims No: 24–1674V
89. Joseph Dusrjah, New York, New York, Court of Federal Claims No: 24–1680V
 90. Tiffany Blohm, De Pere, Wisconsin, Court of Federal Claims No: 24–1681V
 91. Michael T. Wagner, Boscobel, Wisconsin, Court of Federal Claims No: 24–1682V
 92. Eric Sedwick, Nashville, Tennessee, Court of Federal Claims No: 24–1684V
 93. Rachel Aviles, Boston, Massachusetts, Court of Federal Claims No: 24–1685V
 94. Lindsay Maldonado, Toppenish, Washington, Court of Federal Claims No: 24–1686V
 95. Timothy Nowling, Garden City Beach, South Carolina, Court of Federal Claims No: 24–1689V
 96. Katherine Patterson, Raleigh, North Carolina, Court of Federal Claims No: 24–1690V
 97. Ianthie Jayakody, Federal Way, Washington, Court of Federal Claims No: 24–1691V
 98. Cathrine Mistele on behalf of J. M., Los Angeles, California, Court of Federal Claims No: 24–1692V
 99. Alicia Ann Knight, Colorado Springs, Colorado, Court of Federal Claims No: 24–1694V
 100. Charles Jones, La Grande, Oregon, Court of Federal Claims No: 24–1697V
 101. Ashley Loncarich-Boeckman, Tulsa, Oklahoma, Court of Federal Claims No: 24–1698V
 102. Aida Acosta, Howell, Michigan, Court of Federal Claims No: 24–1699V
 103. Valerie Hoff, Atlanta, Georgia, Court of Federal Claims No: 24–1700V
 104. Sofia Gunawan, Phoenix, Arizona, Court of Federal Claims No: 24–1701V
 105. Felicia Markham, Redlands, Texas, Court of Federal Claims No: 24–1702V
 106. Makayla Wagner, St. Ansgar, Iowa, Court of Federal Claims No: 24–1703V
 107. Kimberly Rice, Chicago, Illinois, Court of Federal Claims No: 24–1704V
 108. Jennifer Camacho, Rock Hill, South Carolina, Court of Federal Claims No: 24–1708V
 109. Christopher Budge, White Bear Lake, Minnesota, Court of Federal Claims No: 24–1709V
 110. George Ward, Florence, Kentucky, Court of Federal Claims No: 24–1711V
 111. Heather J. Gardner, Port Huron, Michigan, Court of Federal Claims No: 24–1712V
 112. Maxfel Goodson, Ketchikan, Alaska, Court of Federal Claims No: 24–1713V
 113. Christine Leo, Goshen, New York, Court of Federal Claims No: 24–1716V
 114. Amie Marcott on behalf of A. M., Brownstown Township, Michigan, Court of Federal Claims No: 24–1717V
 115. Karen Kun, Chicago, Illinois, Court of Federal Claims No: 24–1718V
 116. Jennifer Plumley, Bozeman, Montana, Court of Federal Claims No: 24–1721V
 117. Leandra Logston and Cody Logston on behalf of A. G. L., Boston, Massachusetts, Court of Federal Claims No: 24–1724V
 118. Kimberly Pino, Dresher, Pennsylvania, Court of Federal Claims No: 24–1728V
 119. Gregory Fridell, San Diego, California, Court of Federal Claims No: 24–1730V
 120. Virginia Fisher, Hornell, New York, Court of Federal Claims No: 24–1732V
 121. Michael Seck, Boston, Massachusetts, Court of Federal Claims No: 24–1733V
 122. Kaley Stockton, Los Angeles, California, Court of Federal Claims No: 24–1736V
 123. Robyn Boyd, Los Angeles, California, Court of Federal Claims No: 24–1737V
 124. Verdie Atienza, Chesapeake, Virginia, Court of Federal Claims No: 24–1738V
 125. Sabaha Sabi Zagwolsky, Orange, California, Court of Federal Claims No: 24–1739V
 126. Edward Cummings, Philadelphia, Pennsylvania, Court of Federal Claims No: 24–1742V
 127. Daniel Diehl, Fort Knox, Kentucky, Court of Federal Claims No: 24–1743V
 128. Jennifer Credeur, Frisco, Texas, Court of Federal Claims No: 24–1746V
 129. Michael Dugas, Ventura, California, Court of Federal Claims No: 24–1747V
 130. Anife Tashi, Boston, Massachusetts, Court of Federal Claims No: 24–1748V
 131. John Morris, Los Angeles, California, Court of Federal Claims No: 24–1751V
 132. Adrianna Mckeage, Los Angeles, California, Court of Federal Claims No: 24–1752V
 133. Melissa Weber, New York, New York, Court of Federal Claims No: 24–1753V
 134. Kari Morey, Los Angeles, California, Court of Federal Claims No: 24–1754V
 135. Gary L. Tranmer, South Sioux City, Nebraska, Court of Federal Claims No: 24–1755V
 136. Tracey Kubis, Dresher, Pennsylvania, Court of Federal Claims No: 24–1756V
 137. Sonia Bittar, Quincy, Massachusetts, Court of Federal Claims No: 24–1757V
 138. Manuela Sympson, Ames, Iowa, Court of Federal Claims No: 24–1758V
 139. Bryan Payne, New Orleans, Louisiana, Court of Federal Claims No: 24–1759V
 140. Sara A. Morse, Hyde Park, New York, Court of Federal Claims No: 24–1765V
 141. Patricia Pervenanze, Minneapolis, Minnesota, Court of Federal Claims No: 24–1768V
 142. Elizabeth Christensen, Burlington, Washington, Court of Federal Claims No: 24–1769V
 143. Cathy A. Smeal, Ellsworth, Maine, Court of Federal Claims No: 24–1772V
 144. Ryan Stroup, Phoenix, Arizona, Court of Federal Claims No: 24–1775V
 145. Carol Bielski on behalf of Wayne Bielski, Washington, District of Columbia, Court of Federal Claims No: 24–1777V
 146. Kimberly Cross, Richmond, Virginia, Court of Federal Claims No: 24–1778V
 147. Lily McNulty and Conor McNulty on behalf of J.M., Phoenix, Arizona, Court of Federal Claims No: 24–1779V
 148. Mackenzie Larsen, Columbus, Ohio, Court of Federal Claims No: 24–1782V
 149. Clara Trigueros, Woodridge, Illinois, Court of Federal Claims No: 24–1783V
 150. John Lewis Walston, Austin, Texas, Court of Federal Claims No: 24–1785V
 151. Estella Fluaitt, Rockford, Illinois, Court of Federal Claims No: 24–1786V
 152. Gail L. Smith, Englewood, New Jersey, Court of Federal Claims No: 24–1788V
 153. Ryleigh Francis, Phoenix, Arizona, Court of Federal Claims No: 24–1789V
 154. Tyronda Roberson, Woodridge, Illinois, Court of Federal Claims No: 24–1790V
 155. Thomas Judge, New York, New York, Court of Federal Claims No: 24–1793

[FR Doc. 2024–30457 Filed 12–19–24; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Center for Advancing Translational Sciences Advisory Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The Open Session may be accessed by the public from the NIH Videocast at the following link: <https://videocast.nih.gov>.

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 Center for Advancing Translational Sciences Advisory Council.

Date: January 30–31, 2025.

Closed: January 30, 2025, 11:00 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Center for Advancing Translational Sciences, National Institutes of Health, NCI Shady Grove 1E32/1E34, 9609 Medical Center Drive, Rockville, MD 20850, Virtual Meeting.

Open: January 30, 2025, 1:15 p.m. to 4:30 p.m.

Agenda: Report from the Center Director, Clearance of Concept(s), Special Topic presentation.

Address: National Center for Advancing Translational Sciences, National Institutes of Health, NCI Shady Grove 1E32/1E34, 9609 Medical Center Drive, Rockville, MD 20850, Virtual Meeting.

Open: January 31, 2025, 1:00 p.m. to 5:00 p.m.