

information for participating in the webcast is available at the following website: <https://reaganudall.org/news-and-events/events/investigational-drug-labels>.

Registered participants will be sent technical system requirements in advance of the event. It is recommended that you review these technical system requirements before joining the streaming web conference of the public meeting.

FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

*Transcripts:* Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at <https://reaganudall.org/news-and-events/events/investigational-drug-labels>.

#### IV. References

The following references marked with an asterisk (\*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at <https://www.regulations.gov>. References without asterisks are not on public display at <https://www.regulations.gov> because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

- \* 1. European Commission, "EU Guidelines to Good Manufacturing Practice; Medicinal Products for Human and Veterinary Use," Public release date: February 3, 2010 (available at [https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-4/2009\\_06\\_annex13.pdf](https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-4/2009_06_annex13.pdf)).
2. Smith-Gick, J., N. Barnes, R. Barone, et al., "The Near-Term Viability and Benefits of eLabels for Patients, Clinical Sites, and Sponsors," *Therapeutic Innovation and Regulatory Science*, vol. 52(5), pp. 537–545, 2018.
- \* 3. Health Canada, Good Clinical Practices Guidance Document, "Annex 13 to the Current Edition of the Good Manufacturing Practices Guidelines Drugs Used in Clinical Trials," August 7, 2009 (available at [https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-clinical-practices/guidance-documents/annex-13-good-manufacturing-practices-guidelines-drugs-clinical-trials-0036.html#a8\\_7](https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-clinical-practices/guidance-documents/annex-13-good-manufacturing-practices-guidelines-drugs-clinical-trials-0036.html#a8_7)).
- \* 4. FDA, Guidance for Industry and FDA staff, "FDA Acceptance of Foreign Clinical Studies Not Conducted Under an IND; Frequently Asked Questions," March 2012 (available at <https://www.fda.gov/media/83209/download>). For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>.
5. Duhamel, A., M. Thibault, D. Lebel, et al., "Investigational Drug Labeling Variability," *Clinical Trials*, vol. 16(2), pp. 204–213, 2019.
6. Dollinger, C., V. Schwiertz, L. Sarfati, et al., "Simulation of Medication Error Induced by Clinical Trial Drug Labeling: The SIMME-CT Study," *International Journal for Quality in Health Care*, vol. 28(3), pp. 311–315, 2016.
7. Kay, S.C., D.G. Luke, and H.R. Tamer, "ASHP Guidelines for the Management of Investigational Drug Products," *American Journal of Health-System Pharmacy*, vol. 75(8), pp. 561–573, 2018.
- \* 8. ISMP, "Investigational Drugs: Strategies for Sponsors, FDA, and Clinical Sites to Prevent Product-Related Errors (Part II)," Public release date: May 3, 2018 (available at <https://www.ismp.org/resources/investigational-drugs-strategies-sponsors-fda-and-clinical-sites-prevent-product-related>).
- \* 9. ISMP, "Investigational Drugs: Product-Related Issues Pose Significant Challenges (Part I)," Public release date: April 19, 2018 (available at <https://www.ismp.org/resources/investigational-drugs-product-related-issues-pose-significant-challenges-part-i>).
10. Cruz, J.L. and J.N. Brown, "Safety Risks With Investigational Drugs: Pharmacy Practices and Perceptions in the Veterans Affairs Health System," *Therapeutic Advances in Drug Safety*, vol. 6(3), pp. 103–109, 2015.
11. Grissinger, M., "Reducing the Potential for Mistakes With Investigational Drugs," *Pharmacy and Therapeutics*, vol. 36(3), pp. 120–138, 2011.
12. Brown, J.N., S.R. Britnell, A.P. Stivers, et al., "Medication Safety in Clinical Trials: Role of the Pharmacist in Optimizing Practice, Collaboration, and Education To Reduce Errors," *Yale Journal of Biology and Medicine*, vol. 90(1), pp. 125–133, 2017.
- \* 13. ISMP, "Remdesivir Investigational Drug Labeling Confusion," *Acute Care*, vol. 25(9), 2020.
- \* 14. FDA, Draft Guidance for Industry, "Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors," April 2013 (available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-considerations-container-labels-and-carton-labeling-design-minimize>

*medication-errors*). When final, this guidance will represent the FDA's current thinking on this topic. For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>.

Dated: March 11, 2021.

**Lauren K. Roth,**

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–05370 Filed 3–15–21; 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, 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 February 1, 2021, through February 28, 2021. 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 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, Healthcare Systems Bureau, 5600 Fishers Lane, 08N146B, 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,**

*Acting Administrator.*

#### List of Petitions Filed

1. Makaylah Kelly, Englewood, Colorado Court of Federal Claims No: 21-0827V
2. Evelyn Ashford, Washington, District of Columbia, Court of Federal Claims No: 21-0828V
3. David K. McQuinn, Washington, District of Columbia, Court of Federal Claims No: 21-0829V
4. Laura O’Hara, Spring, Texas, Court of Federal Claims No: 21-0830V
5. Peter Weil, Madison, Wisconsin, Court of Federal Claims No: 21-0831V
6. Lisa Carter, Woodbridge, Virginia, Court of Federal Claims No: 21-0832V
7. Laurie Marowski on behalf of A. M., Phoenix, Arizona, Court of Federal Claims No: 21-0834V
8. Jason Gaskin and Tabitha Gaskin on behalf of Jason Gaskin, Jr., Deceased, Rancho Santa Margarita, California, Court of Federal Claims No: 21-0835V
9. Laurie Blake, Washington, District of Columbia, Court of Federal Claims No: 21-0837V
10. Jason Groves, Port Angeles, Washington, Court of Federal Claims No: 21-0838V
11. Denise Oldoni, Augusta, Georgia, Court of Federal Claims No: 21-0839V
12. Tony Moye, Madisonville, Texas, Court of Federal Claims No: 21-0841V
13. Hema Mullur, Austin, Texas, Court of Federal Claims No: 21-0842V
14. Barbara Langburt, Washington, District of Columbia, Court of Federal Claims No: 21-0843V
15. Paul Longo, Washington, District of Columbia, Court of Federal Claims No: 21-0844V
16. Joseph Ned Martinez, Washington, District of Columbia, Court of Federal Claims No: 21-0845V
17. Kimberly Albury, Tampa, Florida, Court of Federal Claims No: 21-0846V
18. Oscar Garner, Milwaukee, Wisconsin, Court of Federal Claims No: 21-0847V
19. Phillip Herrera, Milwaukee, Wisconsin, Court of Federal Claims No: 21-0849V
20. Ivan Boyd, Boston, Massachusetts, Court of Federal Claims No: 21-0850V
21. James D. Woodcock, Greenfield, Indiana, Court of Federal Claims No: 21-0851V
22. Rosalind Paaswell, Boston, Massachusetts, Court of Federal Claims No: 21-0853V
23. Virginia McGee, Boston, Massachusetts, Court of Federal Claims No: 21-0854V
24. Beverly Dye, Newtown, Pennsylvania, Court of Federal Claims No: 21-0855V
25. Yolanda Henderson, Dresher, Pennsylvania, Court of Federal Claims No: 21-0857V
26. Anna Miller and Matthew Miller on behalf of A. M., San Diego, California, Court of Federal Claims No: 21-0858V
27. Alexis Lainez on behalf of Noah Greyson Montoya, Deceased, Apple Valley, California, Court of Federal Claims No: 21-0859V
28. Celeste Bodenbender, Washington, District of Columbia, Court of Federal Claims No: 21-0860V
29. Phyllis K. Alexander, Greensboro, North Carolina, Court of Federal Claims No: 21-0861V
30. Adelyn Diaz De La Rocha, Washington, District of Columbia, Court of Federal Claims No: 21-0862V
31. Ana Rivera Rodriguez, San Juan, Puerto Rico, Court of Federal Claims No: 21-0865V
32. Naomi DeLeon on behalf of N. R., Austin, Texas, Court of Federal Claims No: 21-0866V
33. Allen Bickel, Boston, Massachusetts, Court of Federal Claims No: 21-0867V
34. Darlene Cucinotta, Clermont, Florida, Court of Federal Claims No: 21-0868V
35. Dawn Maxfield, Palm Bay, Florida, Court of Federal Claims No: 21-0869V
36. Dominick Vanore, Reno, Nevada, Court of Federal Claims No: 21-0870V
37. Michelle Mason, Pompano Beach, Florida, Court of Federal Claims No: 21-0871V
38. David Titus, Washington, District of Columbia, Court of Federal Claims No: 21-0875V
39. Mike Rodriguez, Las Vegas, Nevada, Court of Federal Claims No: 21-0876V
40. Jerry D. Keller, Richmond, Kentucky, Court of Federal Claims No: 21-0879V
41. Gina Schueler, Richmond, Kentucky, Court of Federal Claims No: 21-0880V
42. Zehra Rizvi, Irmo, South Carolina, Court of Federal Claims No: 21-0881V
43. Douglas Arricale, Phoenix, Arizona, Court of Federal Claims No: 21-0882V
44. Graham Wilkinson, Washington, District of Columbia, Court of Federal Claims No: 21-0883V
45. Sherry Jeffries Compton on behalf of Joyce E. Jeffries, Memphis, Tennessee, Court of Federal Claims No: 21-0884V
46. Dennis Franklin, Springfield, Minnesota, Court of Federal Claims No: 21-0885V
47. Emilia Ostrowska, Houston, Texas, Court

- of Federal Claims No: 21-0886V
48. Krystal Layman, Chillicothe, Ohio, Court of Federal Claims No: 21-0887V
  49. Margaret Craig, Madisonville, Texas, Court of Federal Claims No: 21-0889V
  50. Paul Bishop, Rochester, New York, Court of Federal Claims No: 21-0891V
  51. Abraham Scott, Flowood, Mississippi, Court of Federal Claims No: 21-0892V
  52. Frank Mares, West Covina, California, Court of Federal Claims No: 21-0893V
  53. Kathleen G. McKenna, Spokane, Wisconsin, Court of Federal Claims No: 21-0895V
  54. Arlene Bourne, Washington, District of Columbia, Court of Federal Claims No: 21-0899V
  55. Della McKeegan, Collierville, Tennessee, Court of Federal Claims No: 21-0900V
  56. Margot Meissner, Boston, Massachusetts, Court of Federal Claims No: 21-0901V
  57. Ingraham Hanahan, Washington, District of Columbia, Court of Federal Claims No: 21-0902V
  58. Brandy Romeo, Dresher, Pennsylvania, Court of Federal Claims No: 21-0903V
  59. Muhand Haddad, Downers Grove, Illinois, Court of Federal Claims No: 21-0904V
  60. Samantha Brotman, New York, New York, Court of Federal Claims No: 21-0905V
  61. Carol Cabral, Girard, Pennsylvania, Court of Federal Claims No: 21-0906V
  62. Sandra Williams, Woodbridge, Virginia, Court of Federal Claims No: 21-0907V
  63. Patricia Merrill, Charlotte, North Carolina, Court of Federal Claims No: 21-0908V
  64. Brenda White, North Lincoln, Kansas, Court of Federal Claims No: 21-0909V
  65. Jennifer Hamilton, Memphis, Tennessee, Court of Federal Claims No: 21-0910V
  66. Kayla Brown, Chesapeake, Virginia, Court of Federal Claims No: 21-0912V
  67. Barbara Kelly, Gainesville, Georgia, Court of Federal Claims No: 2, Colleen Marie Medlock, Hillsboro, Oregon, Court of Federal Claims No: 21-0915V
  69. Diane Blouin, Boston, Massachusetts, Court of Federal Claims No: 21-0919V
  70. Amy Lalla, Cortland, New York, Court of Federal Claims No: 21-0920V
  71. Michael R. Lueck, Greenfield, Wisconsin, Court of Federal Claims No: 21-0923V
  72. Christian M. Gatto, Linwood, New Jersey, Court of Federal Claims No: 21-0924V
  73. Juan F. Ruiz, Jr., Boscobel, Wisconsin, Court of Federal Claims No: 21-0927V
  74. Carissa Feters, Phoenix, Arizona, Court of Federal Claims No: 21-0928V
  75. Amy Congilose, Matthews, North Carolina, Court of Federal Claims No: 21-0929V
  76. Jennifer Kane, Boalsburg, Pennsylvania, Court of Federal Claims No: 21-0930V
  77. Marc Clodfelter, Washington, District of Columbia, Court of Federal Claims No: 21-0931V
  78. Hawke M. Strickland, Waupin, Wisconsin, Court of Federal Claims No: 21-0932V
  79. Kimberly A. MacFeggan, Collierville, Tennessee, Court of Federal Claims No: 21-0933V
  80. Claudia Garcia on behalf of G. G., Oklahoma City, Oklahoma, Court of Federal Claims No: 21-0934V
  81. Katherine O'Brien, Tinton Falls, New Jersey, Court of Federal Claims No: 21-0936V
  82. Robert Willis, Bluffton, South Carolina, Court of Federal Claims No: 21-0938V
  83. Es Mae Rose, Pendleton, Oregon, Court of Federal Claims No: 21-0939V
  84. Jeannie Lowery, Greensboro, North Carolina, Court of Federal Claims No: 21-0940V
  85. Gwendolyn Pilgrim, Washington, District of Columbia, Court of Federal Claims No: 21-0941V
  86. Vienna Giglio, Eastchester, New York, Court of Federal Claims No: 21-0942V
  87. James Russell, Allen Park, Michigan, Court of Federal Claims No: 21-0943V
  88. Sharon Dewyea, Washington, District of Columbia, Court of Federal Claims No: 21-0944V
  89. Justin Hock, Baltimore, Maryland, Court of Federal Claims No: 21-0945V
  90. Clemmie L. Johnson, Boscobel, Wisconsin, Court of Federal Claims No: 21-0946V
  91. Antonio J. Smith, Boscobel, Wisconsin, Court of Federal Claims No: 21-0947V
  92. James Cantafio, Danbury, Connecticut, Court of Federal Claims No: 21-0948V
  93. Emma Fox, Exton, Pennsylvania, Court of Federal Claims No: 21-0949V
  94. Tammy Bosford, Queensbury, New York, Court of Federal Claims No: 21-0950V
  95. Thom Demicco, Loma Linda, California, Court of Federal Claims No: 21-0951V
  96. Debra White, Pacific Grove, California, Court of Federal Claims No: 21-0952V
  97. Tremayne D. Edwards, Milwaukee, Wisconsin, Court of Federal Claims No: 21-0954V
  98. Debra Law, St. Louis, Missouri, Court of Federal Claims No: 21-0956V
  99. Isaiah Jacobs, Scottsdale, Arizona, Court of Federal Claims No: 21-0957V
  100. Glorianna Rennish, Sheboygan, Wisconsin, Court of Federal Claims No: 21-0959V
  101. Jeffrey Flynn, Sunnyside, New York, Court of Federal Claims No: 21-0960V
  102. Steven Marshall, Ruckersville, Virginia, Court of Federal Claims No: 21-0961V
  103. Margaret Spencer, Washington, District of Columbia, Court of Federal Claims No: 21-0962V
  104. Elizabeth Fagan, Beverly Hills, California, Court of Federal Claims No: 21-0963V
  105. Nancy Stolze, Beverly Hills, California, Court of Federal Claims No: 21-0964V
  106. Andera Smith, Beverly Hills, California, Court of Federal Claims No: 21-0965V
  107. Thomas K. O'Connor, New York, New York, Court of Federal Claims No: 21-0966V
  108. Alberto S. Galvan, Waupun, Wisconsin, Court of Federal Claims No: 21-0967V
  109. Felicia Sanchez, Dallas, Texas, Court of Federal Claims No: 21-0968V
  110. Jacqueline Clancy, Ellicott City, Maryland, Court of Federal Claims No: 21-0969V
  111. Magdalena Fernandez, Dallas, Texas, Court of Federal Claims No: 21-0970V
  112. Todd Katz, Dallas, Texas, Court of Federal Claims No: 21-0971V
  113. Kathaleen Lang, Dallas, Texas, Court of Federal Claims No: 21-0972V
  114. Ulrike Mathilde Mueller-Sprout, Dallas, Texas, Court of Federal Claims No: 21-0973V
  115. Sandra Camacho, Dallas, Texas, Court of Federal Claims No: 21-0974V
  116. Andres Visconde, Washington, District of Columbia, Court of Federal Claims No: 21-0977V
  117. Liza Orban, Utica, Michigan, Court of Federal Claims No: 21-0978V
  118. Kimberly Axelrod, Arlington, Virginia, Court of Federal Claims No: 21-0980V
  119. Yazmin Soto, New York, New York, Court of Federal Claims No: 21-0981V
  120. Chih-Jung Chen, Rochester, New York, Court of Federal Claims No: 21-0982V
  121. Kevin Lange, Buffalo, New York, Court of Federal Claims No: 21-0983V
  122. Jillian C. Beccia, Farmington Hills, Michigan, Court of Federal Claims No: 21-0984V
  123. Pamela Clemente, Pittsburgh, Pennsylvania, Court of Federal Claims No: 21-0985V
  124. John W. Vance, Conway, Arkansas, Court of Federal Claims No: 21-0986V
  125. Teresa Scarborough, Tustin, California, Court of Federal Claims No: 21-0987V
  126. Wolfgang R. Moenig and Martina Moenig on behalf of M. M., Farmington Hills, Michigan, Court of Federal Claims No: 21-0993V
  127. Steve Marshall, Englewood, New Jersey, Court of Federal Claims No: 21-0997V
  128. Esperanza Perez, Englewood, New Jersey, Court of Federal Claims No: 21-0998V
  129. Lacy Cloud, Cheyenne, Wyoming, Court of Federal Claims No: 21-0999V
  130. Ashley Parmer, Phoenix, Arizona, Court of Federal Claims No: 21-1000V
  131. Brenna Benjamin on behalf of L. J. R., Ellicott City, Maryland, Court of Federal Claims No: 21-1001V
  132. Jillian Fishburn, Phoenix, Arizona, Court of Federal Claims No: 21-1002V
  133. Evelyn Gonzalez, Woodbridge, Illinois, Court of Federal Claims No: 21-1003V
  134. Aryel Vezzose, Phoenix, Arizona, Court of Federal Claims No: 21-1004V
  135. Beverly Williams, Richardson, Texas, Court of Federal Claims No: 21-1006V

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