

effectiveness and to support claims in approved medical labeling.

The collections of information in 21 CFR 314.50, 314.126, and 601.2 are submitted to FDA to support the medical product's effectiveness and to support claims in approved medical product labeling. The collections of information have been approved under OMB control numbers 0910-0001 and 0910-0338. The collections of information in 21 CFR 312.23 regarding investigational new drug applications, including clinical trial design and study protocols, have been approved under OMB control number 0910-0014. The collections of information in 21 CFR parts 50 and 56 regarding institutional review boards and the protection of human subjects have been approved under OMB control number 0910-0130. The collections of information in 21 CFR part 11 regarding electronic records and signatures have been approved under OMB control number 0910-0303. The collections of information described in FDA's guidance entitled "Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products" (<https://www.fda.gov/media/109951/download>) have been approved under OMB control number 0910-0429.

III. Additional Information

Section 3002 of Title III, Subtitle A, of the 21st Century Cures Act (Pub. L. 114-255) directs FDA to develop patient-focused drug development guidance to address a number of areas, including under section 3002(c)(2):

Methodological approaches that may be used to develop and identify what is important to patients with respect to burden of disease, burden of treatment, and the benefits and risks in the management of the patient's disease.

In addition, FDA committed to meet certain performance goals under the sixth authorization of the Prescription Drug User Fee Act. These goal commitments were developed in consultation with patient and consumer advocates, healthcare professionals, and other public stakeholders, as part of negotiations with regulated industry. Section J.1 of the commitment letter, "Enhancing the Incorporation of the Patient's Voice in Drug Development and Decision-Making" (<https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf>) outlines work, including the development of a series of guidance documents and associated public workshops to facilitate the advancement and use of systematic approaches to collect and use robust and meaningful patient and caregiver input that can more consistently inform

drug development, and, as appropriate, regulatory decision-making.

IV. Electronic Access

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: June 24, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-13952 Filed 6-29-22; 8:45 am]

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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 April 1, 2022, through April 30, 2022. 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, Health 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.

Carole Johnson,
Administrator.

List of Petitions Filed

1. Sherrie Grabp on behalf of Judith Grabp, Deceased, Buffalo, New York, Court of Federal Claims No: 22–0375V
2. Douglas Berman, Boston, Massachusetts, Court of Federal Claims No: 22–0380V
3. Tommy E. Martin, Charlotte, North Carolina, Court of Federal Claims No: 22–0384V
4. Katelin Whiddon, Conway, Arkansas, Court of Federal Claims No: 22–0385V
5. Bridgette Melvin, Oswego, New York, Court of Federal Claims No: 22–0386V
6. Rasheedah Smith, Atlanta, Georgia, Court of Federal Claims No: 22–0387V
7. Sheila Porter, Goodyear, Arizona, Court of Federal Claims No: 22–0389V
8. Mark Humpfer, Schererville, Indiana, Court of Federal Claims No: 22–0390V
9. Darla Wilson, Bloomington, Indiana, Court of Federal Claims No: 22–0393V
10. Maria Schory, Grand Island, New York, Court of Federal Claims No: 22–0394V
11. Josie Ransom, Athens, Georgia, Court of Federal Claims No: 22–0395V
12. Deborah Precil, Maple Shade, New Jersey, Court of Federal Claims No: 22–0396V
13. Rodney Moore, Columbia, Maryland, Court of Federal Claims No: 22–0397V
14. Xania Murray, Denton, Texas, Court of Federal Claims No: 22–0398V
15. Amanda Seigel, Perry, Michigan, Court of Federal Claims No: 22–0399V
16. Jason Brose, Chester Springs, Pennsylvania, Court of Federal Claims No: 22–0401V
17. Krzysztof Kosmicki, Cheyenne, Wyoming, Court of Federal Claims No: 22–0402V
18. Donna Nemuras, Hancock, Maryland, Court of Federal Claims No: 22–0403V
19. Marie Sroka, Walton, New York, Court of Federal Claims No: 22–0405V
20. Brigette Klish, Urbana, Illinois, Court of Federal Claims No: 22–0408V
21. Arlene Weiss, Delray Beach, Florida, Court of Federal Claims No: 22–0409V
22. Ryan Mehm on behalf of C. M., Gaithersburg, Maryland, Court of Federal Claims No: 22–0413V
23. Homer Stine, Ponte Vedra, Florida, Court of Federal Claims No: 22–0415V
24. Mary Platt, Des Moines, Iowa, Court of Federal Claims No: 22–0416V
25. Shelly Vera, Houston, Texas, Court of Federal Claims No: 22–0421V
26. Sherri Smilow, Robbinsville, New Jersey, Court of Federal Claims No: 22–0425V
27. Doris Clark, Madisonville, Kentucky, Court of Federal Claims No: 22–0427V
28. Kelsey Jaranilla and Ryan Jaranilla on behalf of B. J., Salem, Oregon, Court of Federal Claims No: 22–0428V
29. Steven Koruan, Boston, Massachusetts, Court of Federal Claims No: 22–0430V
30. Amy Scarfpin, Westerville, Ohio, Court of Federal Claims No: 22–0431V
31. Antoinette Harris, Heath Springs, South Carolina, Court of Federal Claims No: 22–0432V
32. Christine Madden, Chicago, Illinois, Court of Federal Claims No: 22–0433V
33. Brenda McGaha, Farmington, New Mexico, Court of Federal Claims No: 22–0436V
34. Tammy Beaver, Houston, Texas, Court of Federal Claims No: 22–0439V
35. Emily Cafarella, Phoenix, Arizona, Court of Federal Claims No: 22–0444V
36. Kristen Linton on behalf of C. K., Phoenix, Arizona, Court of Federal Claims No: 22–0445V
37. Beverly Padratzik, Chicago, Illinois, Court of Federal Claims No: 22–0448V
38. Natalie Lawrence, Columbia, South Carolina, Court of Federal Claims No: 22–0450V
39. Katie Pendleton, Dayton, Ohio, Court of Federal Claims No: 22–0454V
40. Margarita Galvan, Houston, Texas, Court of Federal Claims No: 22–0455V
41. Eric Daniel and Chris Daniel on behalf of M. D., Phoenix, Arizona, Court of Federal Claims No: 22–0456V
42. Hanah Hilton on behalf of J. G., Phoenix, Arizona, Court of Federal Claims No: 22–0459V
43. Jason Craige, Langhorne, Pennsylvania, Court of Federal Claims No: 22–0461V
44. Steven Hillstrom, Hancock, Michigan, Court of Federal Claims No: 22–0462V
45. Christopher James, Reston, Virginia, Court of Federal Claims No: 22–0463V
46. Angel Isai Rivera Gonzalez, San Juan, Puerto Rico, Court of Federal Claims No: 22–0464V
47. Corinne Fenn on behalf of R. F., Monroe, North Carolina, Court of Federal Claims No: 22–0465V
48. Larissa Aidone, Islip, New York, Court of Federal Claims No: 22–0467V
49. Lessie Williams, Greensboro, North Carolina, Court of Federal Claims No: 22–0469V
50. Nicholas J. Gauthier, Fort Hood, Texas, Court of Federal Claims No: 22–0470V
51. Gina Crete, Glens Falls, New York, Court of Federal Claims No: 22–0472V
52. Janet Solorio, Sacramento, California, Court of Federal Claims No: 22–0473V
53. John Giangiulio, Devon, Pennsylvania, Court of Federal Claims No: 22–0474V
54. Lisa Ortiz, Ocoee, Florida, Court of Federal Claims No: 22–0475V
55. Patricia Stewart-Robinson, Rego Park, New York, Court of Federal Claims No: 22–0477V
56. Royann Matsel on behalf of the Estate of David Matsel, Kansas City, Missouri, Court of Federal Claims No: 22–0478V
57. Amy Collins on behalf of H. C., Phoenix, Arizona, Court of Federal Claims No: 22–0479V
58. Yul Bernard, Boston, Massachusetts, Court of Federal Claims No: 22–0480V
59. Robert Long, El Cajon, California, Court of Federal Claims No: 22–0481V
60. Claudia Praetel on behalf of M. P., Phoenix, Arizona, Court of Federal Claims No: 22–0482V
61. Abby Vaughn, Barron, Wisconsin, Court of Federal Claims No: 22–0483V
62. Weiwei Dong and Xiangli Kong on behalf of V. K., Fairbanks, Alaska, Court of Federal Claims No: 22–0486V
63. Sharon Scott on behalf of S. S., Phoenix, Arizona, Court of Federal Claims No: 22–0487V

[FR Doc. 2022–14038 Filed 6–29–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; 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: Office of Research Infrastructure Programs Special Emphasis Panel; Member Conflicts: Scientific and Technical Review Board on Biomedical and Behavioral Research Facilities (STOD).

Date: July 28, 2022.

Time: 1:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.