

comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” FDA will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify the information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Jessica Seo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–7699, Fax: 301–847–8533, email: PCNS@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 FDA’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: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. The committee will discuss new drug application (NDA) 216660, for sodium phenylbutyrate/taurursodiol (AMX0035) powder for oral suspension, submitted by Amylyx Pharmaceuticals Inc., for the treatment of amyotrophic lateral sclerosis.

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 on FDA’s website at the time of the advisory committee meeting. Background material and the link to the online teleconference meeting room will be available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before August 23, 2022, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 3:15 p.m. and 4:15 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before August 15, 2022. 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 August 16, 2022.

For press inquiries, please contact the Office of Media Affairs at fdaoma@fda.hhs.gov or 301–796–4540.

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 Jessica Seo (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/ucm111462.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: July 28, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–16570 Filed 8–2–22; 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 June 1, 2022, through June 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. Elizabeth Bacon, Baton Rouge, Louisiana, Court of Federal Claims No: 22-0599V
2. Darby Hoss, Portland, Oregon, Court of Federal Claims No: 22-0600V
3. Julia Kauterman, Berlin, New Jersey, Court of Federal Claims No: 22-0601V
4. Carinna Sharrak, Royal Oak, Michigan, Court of Federal Claims No: 22-0602V
5. Jill Diluigi, Roseville, Michigan, Court of Federal Claims No: 22-0604V

6. Courtney Byrnes, Reisterstown, Maryland, Court of Federal Claims No: 22-0606V
7. Sandra Gill Pace, Central, Louisiana, Court of Federal Claims No: 22-0607V
8. Christine Breen, New York, New York, Court of Federal Claims No: 22-0608V
9. Robin Morrison, Katy, Texas, Court of Federal Claims No: 22-0609V
10. Claudette Hulsey, Hartsville, South Carolina, Court of Federal Claims No: 22-0610V
11. Angela Stewart, Fayetteville, Georgia, Court of Federal Claims No: 22-0611V
12. Imani Corbett, Phoenix, Arizona, Court of Federal Claims No: 22-0612V
13. Linda Butler, Ambler, Pennsylvania, Court of Federal Claims No: 22-0613V
14. Jennifer Callaghan, Voorhees, New Jersey, Court of Federal Claims No: 22-0615V
15. Carmen Hill, East Jordan, Michigan, Court of Federal Claims No: 22-0616V
16. Sharin Elkholy on behalf of L. V., Houston, Texas, Court of Federal Claims No: 22-0618V
17. Kimberly Crysler-Ehlen, Chaska, Minnesota, Court of Federal Claims No: 22-0621V
18. Sharice Brown, Washington, District of Columbia, Court of Federal Claims No: 22-0622V
19. Bala Muccala, Chandler, Arizona, Court of Federal Claims No: 22-0624V
20. Giselle Lewis, Syracuse, New York, Court of Federal Claims No: 22-0628V
21. Brian Thomas, Yokosuka, Japan, Court of Federal Claims No: 22-0631V
22. Jacquese F. Harrell, Boscobel, Wisconsin, Court of Federal Claims No: 22-0635V
23. Terri Jones-White, Auburn Hills, Michigan, Court of Federal Claims No: 22-0637V
24. Earlean Lewis, Macon, Georgia, Court of Federal Claims No: 22-0638V
25. Dana Kendrick on behalf of C. E. K., Spring, Texas, Court of Federal Claims No: 22-0639V
26. Mosel Pearlman-Ramirez, San Rafael, California, Court of Federal Claims No: 22-0640V
27. Richard Rondinaro, Staten Island, New York, Court of Federal Claims No: 22-0643V
28. Michele Holland, Acton, Massachusetts, Court of Federal Claims No: 22-0645V

29. Michael Smith, Matthews, North Carolina, Court of Federal Claims No: 22-0646V
30. Laura Wallace, Bloomington, Minnesota, Court of Federal Claims No: 22-0649V
31. Leah Hutson, Miami, Oklahoma, Court of Federal Claims No: 22-0651V
32. Frances McGovern, Rochester, Minnesota, Court of Federal Claims No: 22-0652V
33. Razia Khan, Astoria, New York, Court of Federal Claims No: 22-0653V
34. Rica Hoskins, Woodbridge, Virginia, Court of Federal Claims No: 22-0654V
35. Veronica Demoss, South Bend, Indiana, Court of Federal Claims No: 22-0655V
36. Joseph Ditro, Huntingtin Valley, Pennsylvania, Court of Federal Claims No: 22-0656V
37. Emmanuel Ayala, East Brunswick, New Jersey, Court of Federal Claims No: 22-0658V
38. Lori Multz, Camarillo, California, Court of Federal Claims No: 22-0660V
39. Joseph Murphy, Bernalillo, New Mexico, Court of Federal Claims No: 22-0661V
40. Richard Newell, Presidio, Texas, Court of Federal Claims No: 22-0662V
41. Rene Newman, Vienna, Virginia, Court of Federal Claims No: 22-0663V
42. Charlotte O'Brien, Babbitt, Minnesota, Court of Federal Claims No: 22-0664V
43. Susan Odell, Alexandria, Minnesota, Court of Federal Claims No: 22-0665V
44. Virginia Perez, Indianapolis, Indiana, Court of Federal Claims No: 22-0666V
45. Ronald Poulin, Buckfield, Maine, Court of Federal Claims No: 22-0667V
46. Jesus Rodriguez, Fort Worth, Texas, Court of Federal Claims No: 22-0668V
47. Connie Rosenkranz, Richland Center, Wisconsin, Court of Federal Claims No: 22-0669V
48. Emma Runyon, Varney, West Virginia, Court of Federal Claims No: 22-0670V
49. Maryam Ahmadi, Newbury Park, California, Court of Federal Claims No: 22-0671V
50. Conceta Murphy, Venice, Florida, Court of Federal Claims No: 22-0672V
51. Jeffrey Bohlmann, Watertown, South Dakota, Court of Federal Claims No: 22-0674V
52. Shannon Robbins, Temple, Texas, Court of Federal Claims No: 22-0675V
53. Gerret Swearingen, Ossian, Indiana, Court of Federal Claims No: 22-0677V
54. Andrew Schaefer, Springfield, Missouri, Court of Federal Claims No: 22-0678V
55. LeeAnn Phillips-McAraw on behalf of K.M., Phoenix, Arizona, Court of Federal Claims No: 22-0679V
56. Jacqueline Schweichler, Edinboro, Pennsylvania, Court of Federal Claims No: 22-0681V
57. Patrick Simmons, Inver Grove Heights, Minnesota, Court of Federal Claims No: 22-0682V
58. Dustin Stamey, Inver Grove Heights, Minnesota, Court of Federal Claims No: 22-0683V
59. Richard Steck, Pittsburgh, Pennsylvania, Court of Federal Claims No: 22-0684V
60. Kimba Stojak, Lindenhurst, Illinois, Court of Federal Claims No: 22-0685V
61. Linda Tan, New York, New York, Court of Federal Claims No: 22-0686V
62. Aaron Thomas, San Diego, California, Court of Federal Claims No: 22-0687V
63. Susan White, West Islip, New York, Court of Federal Claims No: 22-0688V
64. Laura Wunsch, Trempealeau, Wisconsin, Court of Federal Claims No: 22-0689V
65. Nadia Israel, Aurora, Colorado, Court of Federal Claims No: 22-0690V
66. Monica Portee, Columbia, South Carolina, Court of Federal Claims No: 22-0691V
67. Glenna McIntyre, Monroe, Louisiana, Court of Federal Claims No: 22-0692V
68. Dennis Crout, Arlington, Texas, Court of Federal Claims No: 22-0694V
69. Connie Watson, Washington, District of Columbia, Court of Federal Claims No: 22-0695V
70. Jonathan Law, Hampstead, North Carolina, Court of Federal Claims No: 22-0696V
71. Eunice Buffkin, Loris, South Carolina, Court of Federal Claims No: 22-0697V
72. Betty Conn, Cincinnati, Ohio, Court of Federal Claims No: 22-0699V
73. Danielle Polzin, North Mankato, Minnesota, Court of Federal Claims No: 22-0700V
74. Kristina Lemon, Denver, Colorado, Court of Federal Claims No: 22-0701V
75. Michelle Gushue, Hampden, Maine, Court of Federal Claims No: 22-0702V
76. Randi Bovard, Carmichael, California, Court of Federal Claims No: 22-0703V
77. Thomas Meurer, Conway, Arkansas, Court of Federal Claims No: 22-0704V
78. Mark Smith, Jersey City, New Jersey, Court of Federal Claims No: 22-0705V
79. David Meade, Toledo, Ohio, Court of Federal Claims No: 22-0706V
80. Joyce Hammond, Wellesley, Massachusetts, Court of Federal Claims No: 22-0708V
81. Maiah Faapouli, Phoenix, Arizona, Court of Federal Claims No: 22-0709V
82. Julia Foran, Phoenix, Arizona, Court of Federal Claims No: 22-0710V
83. Van Blue, Jr. on behalf of S. B., Lancaster, Pennsylvania, Court of Federal Claims No: 22-0711V
84. Sarah Hamm, Chicago, Illinois, Court of Federal Claims No: 22-0714V
85. Shavannah Ervin, Milwaukee, Wisconsin, Court of Federal Claims No: 22-0716V
86. Denyce Iverson, Cheyenne, Wyoming, Court of Federal Claims No: 22-0718V
87. Jose Fernandez, Greenbrook, New Jersey, Court of Federal Claims No: 22-0719V
88. Selma Taylor, Richmond, Virginia, Court of Federal Claims No: 22-0722V
89. Phyllis Olszewski, Taylor, Michigan, Court of Federal Claims No: 22-0723V
90. Eileen Barton, Washington, District of Columbia, Court of Federal Claims No: 22-0724V
91. John Kiser, Mt. Pleasant, Pennsylvania, Court of Federal Claims No: 22-0726V
92. Michael Henry on behalf of C. H., Phoenix, Arizona, Court of Federal Claims No: 22-0727V
93. Jeffrey Scott Curry, Germantown, Tennessee, Court of Federal Claims No: 22-0729V
94. Christopher Chandler, Savannah, Georgia, Court of Federal Claims No: 22-0730V

[FR Doc. 2022-16613 Filed 8-2-22; 8:45 am]

BILLING CODE 4165-15-P