

with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency 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 to 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 this 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Anuradha Ramamoorthy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903, Anuradha.ramamoorthy@fda.hhs.gov, 240-402-6426.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Clinical Pharmacology Considerations for Human Radiolabeled Mass Balance

Studies.” A human radiolabeled mass balance study is the single most direct study to obtain quantitative and comprehensive information on the absorption, distribution, metabolism, and excretion of an investigational drug in the human body. The mass balance study can provide information to determine the overall pathways of metabolism and excretion of an investigational drug, identify circulating metabolites, and determine the abundance of metabolites relative to the parent or total drug-related exposure. This guidance provides FDA’s recommendations for clinical pharmacology considerations in conducting human radiolabeled mass balance studies during drug development, including: (1) deciding whether and when to conduct the study, (2) designing the study, and (3) reporting the study results.

This guidance finalizes the draft guidance of the same name issued on May 5, 2022 (87 FR 26763). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include: (1) updates to terms used in the guidance to provide clarity, (2) additional references that have been published since the draft guidance was issued, and (3) editorial changes to improve clarity.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on “Clinical Pharmacology Considerations for Human Radiolabeled Mass Balance Studies.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521). The collections of information in 21 CFR 201.57 relating to prescription product labeling requirements have been approved under OMB control number 0910-0572. The collections of information for submission of investigational new drug applications in 21 CFR part 312 have been approved under OMB control number 0910-0014. The collections of information for submission of new drug

applications in 21 CFR part 314 have been approved under OMB control number 0910-0001.

III. Electronic Access

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

Dated: July 15, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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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 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 May 1, 2024, through May 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.

Carole Johnson,
Administrator.

List of Petitions Filed

1. Amanda Harnisch, Phoenix, Arizona, Court of Federal Claims No: 24-0691V
2. Roberta Parker, Nashville, Tennessee, Court of Federal Claims No: 24-0692V
3. Bernard Stewart, Pasadena, Maryland, Court of Federal Claims No: 24-0693V
4. McKenzie R. Miller, Rochester, New York, Court of Federal Claims No: 24-0694V
5. Arianna White, East Lansing, Michigan, Court of Federal Claims No: 24-0697V
6. Jean Modglin, Anna, Illinois, Court of Federal Claims No: 24-0702V
7. William Caruso, Port St. Lucie, Florida, Court of Federal Claims No: 24-0705V
8. Robert Cavallo, Boston, Massachusetts, Court of Federal Claims No: 24-0706V
9. David Tomala, Los Angeles, California, Court of Federal Claims No: 24-0707V
10. Linn Tanzman, Shelter Island, New York, Court of Federal Claims No: 24-0708V
11. Adam Yeoman, Green Bay, Wisconsin, Court of Federal Claims No: 24-0709V
12. Amelia Radovanovici, Durango, Colorado, Court of Federal Claims No: 24-0710V
13. Christina Molnar, Willoughby Hills, Ohio, Court of Federal Claims No: 24-0712V
14. Alex Willenborg, Hyde Park, New York, Court of Federal Claims No: 24-0713V
15. Yolanda Stewart, Clarksville, Tennessee, Court of Federal Claims No: 24-0714V
16. Laura Stevens, Austin, Texas, Court of Federal Claims No: 24-0716V
17. James O’Dell, Boston, Massachusetts, Court of Federal Claims No: 24-0720V
18. Valerie Edwards on behalf of Z. G., New York, New York, Court of Federal Claims No: 24-0722V
19. Richard Roberts, Salida, Colorado, Court of Federal Claims No: 24-0724V
20. Nannie Diggs, Poquoson, Virginia, Court of Federal Claims No: 24-0725V
21. Michelle Emery, Shawnee, Tennessee, Court of Federal Claims No: 24-0726V
22. Jerry Wayne Roden, Chattanooga, Tennessee, Court of Federal Claims No: 24-0729V
23. Anthony Farrell, Peoria, Arizona, Court of Federal Claims No: 24-0731V
24. Aimee Alvarez, Boston, Massachusetts, Court of Federal Claims No: 24-0732V
25. James Rice, Weatherford, Texas, Court of Federal Claims No: 24-0733V
26. Donna Kostuch, White Bear Lake, Minnesota, Court of Federal Claims No: 24-0737V
27. Lori Thompson, Bowling Green, Kentucky, Court of Federal Claims No: 24-0738V
28. Andrew Davidson, San Diego, California, Court of Federal Claims No: 24-0739V
29. Dennis Dombrowski, II, Ortonville, Michigan, Court of Federal Claims No: 24-0741V
30. Tiffany Crider, Jackson, Tennessee, Court of Federal Claims No: 24-0744V
31. Chloi Pampallis, San Francisco, California, Court of Federal Claims No: 24-0745V
32. Anthony Vicari, Lynden, Washington, Court of Federal Claims No: 24-0746V
33. Joan Western, Mount Pleasant, Wisconsin, Court of Federal Claims No: 24-0747V
34. Sherian Smith, Upland, Pennsylvania, Court of Federal Claims No: 24-0748V
35. Madelyn Clark, Crystal Lake, Illinois, Court of Federal Claims No: 24-0749V
36. Roselyne Omwega, Albuquerque, New Mexico, Court of Federal Claims No: 24-0752V
37. Junious Nielsen, Rochester, New York, Court of Federal Claims No: 24-0753V

38. Robert Moseley, Boston, Massachusetts, Court of Federal Claims No: 24-0754V
39. Kathy L. Troen, Pella, Iowa, Court of Federal Claims No: 24-0757V
40. Donnie Yinger, Albany, New York, Court of Federal Claims No: 24-0758V
41. Junious Nielsen, Webster, New York, Court of Federal Claims No: 24-0759V
42. Junious Nielsen, Webster, New York, Court of Federal Claims No: 24-0760V
43. Nancy A. Carroll, Rochester, Minnesota, Court of Federal Claims No: 24-0762V
44. Kristine Albertson, Woodstock, Georgia, Court of Federal Claims No: 24-0765V
45. Neil Saint, Evans, Georgia, Court of Federal Claims No: 24-0768V
46. Rebecca Dobbins, Easley, South Carolina, Court of Federal Claims No: 24-0769V
47. Joanna Ratcliffe, Los Angeles, California, Court of Federal Claims No: 24-0770V
48. Andrea Borah, New York, New York, Court of Federal Claims No: 24-0772V
49. Rhona Page, San Diego, California, Court of Federal Claims No: 24-0774V
50. Michelle DePalma, Phoenix, Arizona, Court of Federal Claims No: 24-0776V
51. Jessica Corso, Simpsonville, South Carolina, Court of Federal Claims No: 24-0777V
52. Jennifer Allen, Mason, Ohio, Court of Federal Claims No: 24-0778V
53. Brittany Smith-Gordon, Warminster, Pennsylvania, Court of Federal Claims No: 24-0779V
54. Saeeda Syed, Goodyear, Arizona, Court of Federal Claims No: 24-0780V
55. Simone Bui, Newburyport, Massachusetts, Court of Federal Claims No: 24-0783V
56. Ashley Phillips on behalf of E. A., Los Angeles, California, Court of Federal Claims No: 24-0784V
57. Ella Coleman-Artz, Coalport, Pennsylvania, Court of Federal Claims No: 24-0785V
58. Rebecca Feller, Council Bluffs, Iowa, Court of Federal Claims No: 24-0786V
59. Susan DiMillo, Lockport, New York, Court of Federal Claims No: 24-0789V
60. Ronald Samson, Council Bluffs, Iowa, Court of Federal Claims No: 24-0790V
61. Eric Gervasi, Philadelphia, Pennsylvania, Court of Federal Claims No: 24-0791V
62. Julie Ann Kueber on behalf of S. K., Indianapolis, Indiana, Court of Federal Claims No: 24-0793V
63. Michaela Strickland, Johnson City, Tennessee, Court of Federal Claims No: 24-0794V
64. Kelsey Leeman, Damariscotta, Maine, Court of Federal Claims No: 24-0796V
65. Timothy Kirkwood, Orlando, Florida, Court of Federal Claims No: 24-0798V
66. David Trainor, East Bridgewater, Massachusetts, Court of Federal Claims No: 24-0801V
67. Jason Horn, Woodridge, Illinois, Court of Federal Claims No: 24-0802V
68. Yulia Ogorodnikova on behalf of L.O., Phoenix, Arizona, Court of Federal Claims No: 24-0803V
69. Isak Ladegaard, Champaign, Illinois, Court of Federal Claims No: 24-0804V
70. Deatrice F. Ruff, Waxhaw, North Carolina, Court of Federal Claims No: 24-0806V
71. Sherry Ellsworth, Lumberton, North Carolina, Court of Federal Claims No: 24-0812V
72. Judith Gratton, Holliston, Massachusetts, Court of Federal Claims No: 24-0813V
73. Rachel Tupitza, Erie, Pennsylvania, Court of Federal Claims No: 24-0814V
74. Haley Labian, Kalamazoo, Wisconsin, Court of Federal Claims No: 24-0818V
75. Marilenis Perez, Boston, Massachusetts, Court of Federal Claims No: 24-0820V
76. Charles Tucker, Hines, Illinois, Court of Federal Claims No: 24-0821V
77. Steven Williams, Washington, District of Columbia, Court of Federal Claims No: 24-0822V
78. Claire Forchheimer, San Jose, California, Court of Federal Claims No: 24-0823V
79. Edward Vincent Russell, Morehead City, North Carolina, Court of Federal Claims No: 24-0824V
80. Lisa West-Thomas, Tacoma, Washington, Court of Federal Claims No: 24-0827V
81. Colleen Ortiz, Manahawkin, New Jersey, Court of Federal Claims No: 24-0828V
82. Michael Clayton, Aurora, Colorado, Court of Federal Claims No: 24-0829V
83. Melissa Ward, Cantonment, Florida, Court of Federal Claims No: 24-0830V
84. Aline Crawford, Chalmette, Louisiana, Court of Federal Claims No: 24-0831V
85. Christopher Seter, Franklin, Tennessee, Court of Federal Claims No: 24-0832V
86. Louis Quick, Lakeville, Minnesota, Court of Federal Claims No: 24-0833V
87. Jennifer Kuch, Saginaw, Michigan, Court of Federal Claims No: 24-0835V
88. Yves Boyer, New York, New York, Court of Federal Claims No: 24-0838V
89. Celeste Sandbank, Roseville, California, Court of Federal Claims No: 24-0839V
90. Eugene Gryga, Bryn Mawr, Pennsylvania, Court of Federal Claims No: 24-0841V
91. Jamie Drake, Newport News, Virginia, Court of Federal Claims No: 24-0842V
92. Christy Lantz, Salisbury, Maryland, Court of Federal Claims No: 24-0844V
93. Tracy Paustian on behalf of J. P., Los Angeles, California, Court of Federal Claims No: 24-0846V
94. Mary Annalee Hull, Honolulu, Hawaii, Court of Federal Claims No: 24-0847V

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

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