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: Jack Dan, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6200, Silver Spring, MD 20993, 240–402–6940.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biologic product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human biologic product VOWST (fecal microbiota spores, live-brpk). VOWST is indicated to prevent the recurrence of *Clostridioides difficile* infection (CDI) in individuals 18 years of age and older following antibacterial treatment for recurrent CDI. Subsequent to this approval, the USPTO received patent term restoration applications for VOWST (U.S. Patent Nos. 9,011,834; 9,180,147; 9,446,080) from Seres Therapeutics, Inc., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated February 6, 2024, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of VOWST represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for VOWST is 2,941 days. Of this time, 2,697 days occurred during the testing phase of the regulatory review period, while 244 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* April 9, 2015. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on April 9, 2015.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* August 26, 2022. FDA has verified the applicant's claim that the biologics license application (BLA) for VOWST (BLA B125757/0) was initially submitted on August 26, 2022.

3. *The date the application was approved:* April 26, 2023. FDA has verified the applicant's claim that BLA B125757/0 was approved on April 26, 2023.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,177 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: June 11, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–11039 Filed 6–13–25; 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, Division of Injury Compensation Programs, 5600 Fishers Lane, Room 8W–25A, Rockville, Maryland 20857; 1–800–338–2382, or visit our website at: *https://www.hrsa.gov/vaccine-compensation*.

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, 2025, through May 31, 2025. 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.

Thomas J. Engels,

Administrator.

List of Petitions Filed

1. Skyla Waddell, Albemarle, North Carolina, Court of Federal Claims No: 25–0751V
2. Kyana Lewis and Shawn Burks on behalf of A. C. B., Fairfax, Virginia, Court of Federal Claims No: 25–0752V
3. Susan Green on behalf of Estate of Jack Benmayor, Deceased, Cincinnati, Ohio, Court of Federal Claims No: 25–0753V
4. Julie Bansch-Wickert, Lone Tree, Colorado, Court of Federal Claims No: 25–0754V
5. Nicole Companik, Chicago, Illinois, Court of Federal Claims No: 25–0755V
6. Holly Stroot, Madison, Wisconsin, Court of Federal Claims No: 25–0756V
7. Eric Tasker, Annapolis, Maryland, Court of Federal Claims No: 25–0757V
8. Amal Helen Zayed, Bolingbrook, Illinois, Court of Federal Claims No: 25–0758V
9. Jacob Rosenfeld, Deerfield, Illinois, Court of Federal Claims No: 25–0759V
10. Korina DeHerrera, Ephrata, Washington, Court of Federal Claims No: 25–0762V
11. Deanna Sofie, Dresher, Pennsylvania, Court of Federal Claims No: 25–0764V
12. Mariah Burlew, Manvel, Texas, Court of Federal Claims No: 25–0765V
13. Josh Neaf, Alpharetta, Georgia, Court of Federal Claims No: 25–0767V
14. Sammie L. Thurman, Greensboro, North Carolina, Court of Federal Claims No: 25–0768V
15. Vicki Lipka, Sun Prairie, Wisconsin, Court of Federal Claims No: 25–0769V
16. Barry Averill, Bayport, Texas, Court of Federal Claims No: 25–0771V
17. Jason Elliott, Boston, Massachusetts, Court of Federal Claims No: 25–0773V
18. Aafia Malik, Bayshore, New York, Court of Federal Claims No: 25–0775V
19. Paul Andrew MacLeod, Wellesley, Massachusetts, Court of Federal Claims No: 25–0776V
20. Sparkle Reese, Snellville, Georgia, Court of Federal Claims No: 25–0778V
21. Susan M. LaPointe, Saratoga Springs, New York, Court of Federal Claims No: 25–0779V
22. Jaime Capener, Bountiful, Utah, Court of Federal Claims No: 25–0780V
23. Chandra Thomas, Germantown, Tennessee, Court of Federal Claims No: 25–0781V
24. Alexander Joe Shogan, Jr., Spokane, Washington, Court of Federal Claims No: 25–0784V
25. Linda Mays, Midlothian, Virginia, Court of Federal Claims No: 25–0788V
26. Deanna Wake, Springfield, Missouri, Court of Federal Claims No: 25–0789V
27. Patricia Combs, Phoenix, Arizona, Court of Federal Claims No: 25–0792V
28. Leslie Watkins, Spokane, Washington, Court of Federal Claims No: 25–0795V
29. Nancy Comello, Madison, Wisconsin, Court of Federal Claims No: 25–0796V
30. Kristie Kimmons, Lima, Ohio, Court of Federal Claims No: 25–0798V
31. Rajiv Yandrapati on behalf of N.Y., Houston, Texas, Court of Federal Claims No: 25–0799V
32. Deborah Smyth, Lawrenceville, New Jersey, Court of Federal Claims No: 25–0801V
33. Zachary Menshew, San Antonio, Texas, Court of Federal Claims No: 25–0803V
34. Susan Goff, Chico, California, Court of Federal Claims No: 25–0806V
35. Rebekah Ferguson, New York, New York, Court of Federal Claims No: 25–0807V
36. Charlotte Kahen, Los Angeles, California, Court of Federal Claims No: 25–0808V
37. Kimberly Davidson, Cudahy, Wisconsin, Court of Federal Claims No: 25–0810V
38. Dana Hughes, Santa Barbara, California, Court of Federal Claims No: 25–0812V
39. Shane Silverman, Stratford, Connecticut, Court of Federal Claims No: 25–0813V
40. Brandi Schrader, Grand Rapids, Michigan, Court of Federal Claims No: 25–0815V

41. Douglas Rollins, Mt. Juliet, Tennessee, Court of Federal Claims No: 25–0817V
42. Cynthia Feuling, Oconomowoc, Wisconsin, Court of Federal Claims No: 25–0820V
43. Michelle Purdy, Nebraska City, Nebraska, Court of Federal Claims No: 25–0821V
44. Bianca Chery, Brockton, Massachusetts, Court of Federal Claims No: 25–0822V
45. Blair Leishman, American Fork, Utah, Court of Federal Claims No: 25–0823V
46. Nethaniel Amanfo, Marietta, Georgia, Court of Federal Claims No: 25–0824V
47. Susan Bohall, Denham Springs, Louisiana, Court of Federal Claims No: 25–0825V
48. Prudensiana Lewis, Katy, Texas, Court of Federal Claims No: 25–0829V
49. Edessa Katie Daniel, Los Angeles, California, Court of Federal Claims No: 25–0833V
50. Shalandra Quick, Chicago, Illinois, Court of Federal Claims No: 25–0834V
51. Paige Crum, Springfield, Illinois, Court of Federal Claims No: 25–0835V
52. Michael Bruno, Long Island, New York, Court of Federal Claims No: 25–0836V
53. Susan Vasileff, Sturgeon, Missouri, Court of Federal Claims No: 25–0837V
54. Elizabeth Stelly, City of Industry, California, Court of Federal Claims No: 25–0838V
55. Thomas Church, III, Edgerton, Minnesota, Court of Federal Claims No: 25–0839V
56. Curtis Waits, Redgranite, Wisconsin, Court of Federal Claims No: 25–0840V
57. Marcus Bunton, Bowling Green, Kentucky, Court of Federal Claims No: 25–0841V
58. Jose Antonio Inoa Almonte, Stormville, New York, Court of Federal Claims No: 25–0843V
59. Larry Miller, American Canyon, California, Court of Federal Claims No: 25–0844V
60. Betsy File, Salisbury, North Carolina, Court of Federal Claims No: 25–0845V
61. Nadya Lazarev, New York, New York, Court of Federal Claims No: 25–0846V
62. Janette Glaser, Huntington Beach, California, Court of Federal Claims No: 25–0847V
63. Melvin L. Terry, Allouez, Wisconsin, Court of Federal Claims No: 25–0848V
64. Kyle Muro, Berkeley, California, Court of Federal Claims No: 25–0849V
65. Marci Neustadt, Westlake Village, California, Court of Federal Claims No: 25–0854V
66. Nicole Wood, Woodridge, Illinois, Court of Federal Claims No: 25–0856V
67. Mecquon J. Jones, Fox Lake, Wisconsin, Court of Federal Claims No: 25–0857V
68. Jose Burgos, Dresher, Pennsylvania, Court of Federal Claims No: 25–0860V
69. LaAsia Benford, Acworth, Georgia, Court of Federal Claims No: 25–0861V
70. David Bye, San Francisco, California, Court of Federal Claims No: 25–0862V
71. Gary Sunderland, Dresher, Pennsylvania, Court of Federal Claims No: 25–0863V
72. John A. Rafter, Jr., Portland, Oregon, Court of Federal Claims No: 25–0864V
73. Julie Wakely, Colts Neck, New Jersey, Court of Federal Claims No: 25–0866V
74. Haley Whisenhunt, Chagrin Falls, Ohio, Court of Federal Claims No: 25–0868V
75. Tanya Nelson, Dresher, Pennsylvania, Court of Federal Claims No: 25–0869V
76. Lisa Alber, Dresher, Pennsylvania, Court of Federal Claims No: 25–0870V
77. Kenneth Paciocco, Schertz, Texas, Court of Federal Claims No: 25–0873V
78. Mitchell L. Katzman, Raleigh, North Carolina, Court of Federal Claims No: 25–0879V
79. Cheri Ronan, Dresher, Pennsylvania, Court of Federal Claims No: 25–0880V
80. Ednaly Meza, New York, New York, Court of Federal Claims No: 25–0881V
81. Cynthia Burke, Ferndale, Michigan, Court of Federal Claims No: 25–0884V
82. Nicole Strong, Cedar Springs, Michigan, Court of Federal Claims No: 25–0885V
83. Dawnetta Hayes, Cincinnati, Ohio, Court of Federal Claims No: 25–0886V
84. Michael Boddie, Danville, Pennsylvania, Court of Federal Claims No: 25–0887V
85. Justin Chambers, Bee Cave, Texas, Court of Federal Claims No: 25–0888V
86. Laura Day, Macon, Georgia, Court of Federal Claims No: 25–0889V
87. Taneshia Kendrick on behalf of C.C., Washington, District of Columbia, Court of Federal Claims No: 25–0892V
88. Meaghan Bartlett, Woodridge, Illinois, Court of Federal Claims No: 25–0893V
89. Nicholas Hobbs, Charleston, South Carolina, Court of Federal Claims No: 25–0894V
90. Beth Casteel on behalf of B.C., Denver, Colorado, Court of Federal Claims No: 25–0896V
91. Shari Wilson, Lowell, Massachusetts, Court of Federal Claims No: 25–0897V
92. Shari Smith-Jackson, Dresher, Pennsylvania, Court of Federal Claims No: 25–0898V
93. Maryalice Omokeye Moses, Beverly Hills, California, Court of Federal Claims No: 25–0899V
94. Kathleen Tennaro, Woodridge, Illinois, Court of Federal Claims No: 25–0901V
95. Aubrey L. Hazlett, Raleigh, North Carolina, Court of Federal Claims No: 25–0903V
96. Julie Eusebio, Brookfield, Wisconsin, Court of Federal Claims No: 25–0904V
97. Sara Faux, Dresher, Pennsylvania, Court of Federal Claims No: 25–0905V
98. Allen Barber, Woodridge, Illinois, Court of Federal Claims No: 25–0906V
99. Greer Gisy, Richmond, Virginia, Court of Federal Claims No: 25–0907V
100. Thien Danh, Woodridge, Illinois, Court of Federal Claims No: 25–0908V
101. Russell Senn, White Bear Lake, Minnesota, Court of Federal Claims No: 25–0909V
102. Shara Harbin, Fayetteville, Georgia, Court of Federal Claims No: 25–0911V
103. Rina Mais, Glen Rock, New Jersey, Court of Federal Claims No: 25–0914V
104. Christy Bitterling on behalf of J.B., Los Angeles, California, Court of Federal Claims No: 25–0923V
105. Joshua Carson, Overland Park, Kansas, Court of Federal Claims No: 25–0924V
106. Jerine Coley, Dresher, Pennsylvania, Court of Federal Claims No: 25–0925V
107. Becky Dorris, Dresher, Pennsylvania, Court of Federal Claims No: 25–0927V

[FR Doc. 2025–11046 Filed 6–13–25; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally funded research for the benefit of the public health.

FOR FURTHER INFORMATION CONTACT: Licensing information may be obtained by emailing the licensing contact Michael Shmilovich, Esq.; 301–435–5019; *shmilovm@nih.gov,* at the National Heart, Lung, and Blood, Office of Technology Transfer and Development, 31 Center Drive, Room 4A25, MSC2479, Bethesda, MD 20892–2479. A signed Confidential Disclosure Agreement may be required to receive any unpublished information.

SUPPLEMENTARY INFORMATION: This notice is in accordance with 35 U.S.C. 209 and 37 CFR part 404. Technology description follows.

Reversibly Photo-Switchable Fluorescent Proteins for Long-Term Imaging of Live Specimen

Available for research uses, collaboration, and further development are non-cytotoxic reversibly photo-switchable fluorescent mutant proteins that may be locked in a state of high brightness, which may be useful for long-term biomedical applications at routine laser power intensity. Additionally, these proteins offer quick self-recovery of peak fluorescence, which may be useful for imaging of rapid cellular processes.

Inventors

- Vitaly Boyko, Ph.D. (NIBIB)
- George Patterson, Ph.D. (NIBIB)
- Md Abdul Kader Sagar, Ph.D. (NIBIB)

Potential Applications

- Long-term imaging of live specimen, including light-sensitive specimen
- Probe for high-throughput screening applications
- Fluorescent marker in biomedical screening protocols