A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug 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 drug 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 drug product, GALAFOLD (migalastat) indicated for the treatment of adults with a confirmed diagnosis of Fabry Disease and an amenable galactosidase alpha gene variant based on in vitro assay data. This indication is approved under accelerated approval based on reduction in kidney interstitial capillary cell globotriaosylceramide substrate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. Subsequent to this approval, the USPTO received patent term restoration applications for GALAFOLD (U.S. Patent Nos. 8,592,362 and 9,000,011) from Amicus Therapeutics, Inc. and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated October 29, 2019, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of GALAFOLD 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 GALAFOLD is 5,132 days. Of this time, 4,891 days occurred during the testing phase of the regulatory review period, while 241 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 (FD&C Act) (21 U.S.C. 355(i)) became effective:* July 24, 2004. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on July 24, 2004.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* December 13, 2017. FDA has verified the applicant's claim that the new drug application (NDA) for GALAFOLD (NDA 208623) was initially submitted on December 13, 2017.

3. *The date the application was approved:* August 10, 2018. FDA has verified the applicant's claim that NDA 208623 was approved on August 10, 2018.

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 applications for patent extension, this applicant seeks 732 days or 980 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: March 17, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–05897 Filed 3–21–23; 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, 2023, through February 28, 2023. 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, 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. Thomas Fiumara, Medford, Massachusetts, Court of Federal Claims No: 23–0138V
2. Darren J. Bunton, Indianapolis, Indiana, Court of Federal Claims No: 23–0139V
3. Christina Orton, Phoenix, Arizona, Court of Federal Claims No: 23–0140V
4. Teagan Grabish, Lynden, Washington, Court of Federal Claims No: 23–0141V
5. Samantha Seager, Phoenix, Arizona, Court of Federal Claims No: 23–0142V
6. Sonya Davee, Mattoon, Illinois, Court of Federal Claims No: 23–0148V
7. Ariane Yango on behalf of N.Y., San Jose, California, Court of Federal Claims No: 23–0150V
8. Anthony Blei, Phoenix, Arizona, Court of Federal Claims No: 23–0151V
9. Melinda Adams, Portsmouth, Ohio, Court of Federal Claims No: 23–0153V
10. Barbara Bennett, Hudson, New York, Court of Federal Claims No: 23–0154V,
11. Huda Ahmed, Elmhurst, Illinois, Court of Federal Claims No: 23–0155V
12. Kristine Zuggi on behalf of I.Z., Deceased, Phoenix, Arizona, Court of Federal Claims No: 23–0161V
13. John Jennings, Boston, Massachusetts, Court of Federal Claims No: 23–0162V
14. Matthew J. Koehler, Rochester, New York, Court of Federal Claims No: 23–0163V
15. Ralph Devito, Manchester, New Jersey, Court of Federal Claims No: 23–0164V
16. Emily Mercer, Phoenix, Arizona, Court of Federal Claims No: 23–0168V
17. Haley Phillippi, Phoenix, Arizona, Court of Federal Claims No: 23–0169V
18. Edward Ladwig, Boston, Massachusetts, Court of Federal Claims No: 23–0170V
19. Charles Lindsey, Lawrenceville, Georgia, Court of Federal Claims No: 23–0171V
20. Claire Paul, Atlanta, Georgia, Court of Federal Claims No: 23–0172V
21. Aaron Ford, Phoenix, Arizona, Court of Federal Claims No: 23–0177V
22. Cristina Frank, Pennsville, New Jersey, Court of Federal Claims No: 23–0178V
23. Hyun Lee, Kernersville, North Carolina, Court of Federal Claims No: 23–0179V
24. Karen McLaughlin, East Ridge, Tennessee, Court of Federal Claims No: 23–0180V
25. Amy Vanus, Dresher, Pennsylvania, Court of Federal Claims No: 23–0181V
26. Aiman Al-Hiyari, Rochester, New York, Court of Federal Claims No: 23–0183V
27. Oneil Walker, New Haven, Connecticut, Court of Federal Claims No: 23–0184V
28. Patricia Corcoran, Brewster, New York, Court of Federal Claims No: 23–0186V
29. Molly McBride, Columbia, Missouri, Court of Federal Claims No: 23–0190V
30. Amie Luk, Katy, Texas, Court of Federal Claims No: 23–0191V
31. Dale McCormick, Bryan, Ohio, Court of Federal Claims No: 23–0193V
32. Joseph Meier, Walnut Creek, California, Court of Federal Claims No: 23–0195V
33. Ann Tonjes, Westmont, Illinois, Court of Federal Claims No: 23–0196V
34. Krystel Hannon, Spartanburg, South Carolina, Court of Federal Claims No: 23–0197V
35. Ashlee M. Hong, Thousand Oaks, California, Court of Federal Claims No: 23–0198V
36. James McGinnis, Waynesboro, Virginia, Court of Federal Claims No: 23–0199V
37. Lindsay Anderson on behalf of A.B., Indianapolis, Indiana, Court of Federal Claims No: 23–0200V
38. Michele Plucinsky, Plantation, Florida, Court of Federal Claims No: 23–0201V
39. Patricia Baumann, Dunkirk, Maryland, Court of Federal Claims No: 23–0204V
40. Erny Pope, Leesburg, Virginia, Court of Federal Claims No: 23–0205V
41. Julie Johnson, Rochester, Minnesota, Court of Federal Claims No: 23–0206V
42. Tracy Chapman, Jacksonville, Florida, Court of Federal Claims No: 23–0207V
43. Julia Hill, Lakewood, Washington, Court of Federal Claims No: 23–0208V
44. Lewis von Almen, Addison, Illinois, Court of Federal Claims No: 23–0212V
45. Melanie Hoard on behalf of R.H., Phoenix, Arizona, Court of Federal Claims No: 23–0213V
46. Jamie Walton, Houston, Texas, Court of Federal Claims No: 23–0214V
47. Jean Francois Daneault, Westfield, New Jersey, Court of Federal Claims No: 23–0215V
48. Anson K. Au, Sacramento, California, Court of Federal Claims No: 23–0216V
49. Christy Allen on behalf of E.A., Phoenix, Arizona, Court of Federal Claims No: 23–0219V
50. Annalise Gratovich, Phoenix, Arizona, Court of Federal Claims No: 23–0220V
51. Tricia Unrath on behalf of A.U., Phoenix, Arizona, Court of Federal Claims No: 23–0221V
52. Taryn Keeshan on behalf of L.K., Phoenix, Arizona, Court of Federal Claims No: 23–0223V
53. Ronald Havens, Arcadia, California, Court of Federal Claims No: 23–0225V
54. Samantha Dotson, Cynthiana, Kentucky, Court of Federal Claims No: 23–0227V
55. Jennifer Barrios and Michael Barrios on behalf of B.H.B., Long Beach, California, Court of Federal Claims No: 23–0230V
56. Aklilu Keflezighi, La Mesa, California, Court of Federal Claims No: 23–0233V
57. Rivkalaia Rokeach, Brooklyn, New York, Court of Federal Claims No: 23–0234V
58. Debbie Nease Bohannon on behalf of Braydon Bohannon, Oakdale, California, Court of Federal Claims No: 23–0235V
59. Antonia Dejesus, Englewood, New Jersey, Court of Federal Claims No: 23–0236V
60. Lisa Kurdziel, Hoboken, New Jersey, Court of Federal Claims No: 23–0237V

61. Lee Yuill, Huntsville, Alabama, Court of Federal Claims No: 23–0238V
62. Jose Garcia, Dinuba, California, Court of Federal Claims No: 23–0240V
63. Nicholas Watkins, Rockford, Michigan, Court of Federal Claims No: 23–0241V
64. Timothy Alexander, Albuquerque, New Mexico, Court of Federal Claims No: 23–0242V
65. Barry Griffiths, Manahawkin, New Jersey, Court of Federal Claims No: 23–0243V
66. Karol Schaeffer, York, Pennsylvania, Court of Federal Claims No: 23–0244V
67. Dreama Cleaver, Bellefontaine, Ohio, Court of Federal Claims No: 23–0245V
68. Kristen McCafferty, Phoenix, Arizona, Court of Federal Claims No: 23–0246V
69. Jennifer M. Cangas, Davenport, Iowa, Court of Federal Claims No: 23–0248V
70. Don Chambers, Abilene, Texas, Court of Federal Claims No: 23–0249V
71. Velinda Baker, Dayton, Ohio, Court of Federal Claims No: 23–0250V
72. Alvin Moody, Farmington, Connecticut, Court of Federal Claims No: 23–0251V
73. Benjamin Kane, Newburyport, Massachusetts, Court of Federal Claims No: 23–0252V
74. Peggy Evans, Dacula, Georgia, Court of Federal Claims No: 23–0254V
75. Richa Sharma, Reno, Nevada, Court of Federal Claims No: 23–0255V
76. Mary Ann Locke, Rochester, New York, Court of Federal Claims No: 23–0256V
77. Joseph Hernandez, West Bend, Wisconsin, Court of Federal Claims No: 23–0257V
78. Michael Erhart, Ottawa, Illinois, Court of Federal Claims No: 23–0258V
79. Andrea Walker, Washington, District of Columbia, Court of Federal Claims No: 23–0259V
80. Janice Caraballo, Waterbury, Connecticut, Court of Federal Claims No: 23–0260V
81. Nadia Noel, Phoenix, Arizona, Court of Federal Claims No: 23–0261V
82. Kristilee Maiella, Phoenix, Arizona, Court of Federal Claims No: 23–0262V
83. Vernon Scott, Rochester Hills, Michigan, Court of Federal Claims No: 23–0264V
84. Aaron Labelle, Marquette, Michigan, Court of Federal Claims No: 23–0265V
85. Shiloh Williams, Phoenix, Arizona, Court of Federal Claims No: 23–0266V
86. Andrea Leathers, Phoenix, Arizona, Court of Federal Claims No: 23–0268V
87. Dari Matilsky, Pomona, New York, Court of Federal Claims No: 23–0269V
88. Oana Repede, Raleigh, North Carolina, Court of Federal Claims No: 23–0270V
89. Wendy Newton, Boston, Massachusetts, Court of Federal Claims No: 23–0271V
90. Steele Campbell, Gilbert, Arizona, Court of Federal Claims No: 23–0272V
91. Doris Sawyers, Waynesboro, Mississippi, Court of Federal Claims No: 23–0273V
92. Debra Inman, Farmington, Illinois, Court of Federal Claims No: 23–0274V
93. Michael Edson, Pasadena, California, Court of Federal Claims No: 23–0275V
94. Kristen Hamlin, Greensboro, North Carolina, Court of Federal Claims No: 23–0278V
95. Eugene Lorenzo Wilson, New Lisbon, Wisconsin, Court of Federal Claims No: 23–0279V
96. Ryland Beutz, St. Cloud, Minnesota, Court of Federal Claims No: 23–0283V
97. Michael Ibarra, Houston, Texas, Court of Federal Claims No: 23–0284V
98. Srilatha Rachan, Mount Royal, New Jersey, Court of Federal Claims No: 23–0286V
99. Spencer Thornton, Castle Rock, Colorado, Court of Federal Claims No: 23–0287V
100. Thomas Worrell, Houston, Texas, Court of Federal Claims No: 23–0289V
101. Cathy Burgard, Mukilteo, Washington, Court of Federal Claims No: 23–0290V
102. Jordan Riccardi and Kiley Riccardi on behalf of G.R., Lakewood Ranch, Florida, Court of Federal Claims No: 23–0291V
103. Demonta L. Hambright. Milwaukee, Wisconsin, Court of Federal Claims No: 23–0292V
104. Samuel Smith and Jessica Smith on behalf of J.S., Sarasota, Florida, Court of Federal Claims No: 23–0293V
105. Annette Joseph-Gabriel and Steeve Joseph-Gabriel on behalf of A.J.G., Sarasota, Florida, Court of Federal Claims No: 23–0297V
106. Jon Eric Jensen, Chicago, Illinois, Court of Federal Claims No: 23–0299V

[FR Doc. 2023–05851 Filed 3–21–23; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

''Low-Income Levels'' Used for Various Health Professions and Nursing Programs Authorized in the Public Health Service Act

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HRSA is updating income levels used to identify a ''low-income family'' for the purpose of determining eligibility for programs that provide health professions and nursing training to individuals from disadvantaged backgrounds. These various programs are authorized in the Public Health Service Act. HHS periodically publishes in the **Federal Register**, low-income levels to be used by institutions receiving grants or cooperative agreement awards to determine eligibility for programs providing training for disadvantaged individuals, individuals from disadvantaged backgrounds, or individuals from low-income families.

SUPPLEMENTARY INFORMATION: Many health professions and nursing grant and cooperative agreement awardees use the low-income levels to determine whether potential program participants are from economically disadvantaged backgrounds and would be eligible to participate in the program, as well as to determine the amount of funding individuals receive. Awards are generally made to accredited schools of medicine, osteopathic medicine, public health, dentistry, pharmacy, allied health, and nursing; public or private nonprofit schools which offer graduate programs in behavioral health and mental health practice; and other public or private nonprofit health or educational entities to assist individuals from disadvantaged backgrounds and disadvantaged students to enter and graduate from health professions and nursing schools. Some programs provide for the repayment of health professions or nursing education loans for students from disadvantaged backgrounds and disadvantaged students.

A ''low-income family/household'' for programs included in titles III, VII, and VIII of the Public Health Service Act is defined as having an annual income that does not exceed 200 percent of HHS's poverty guidelines. A family is a group of two or more individuals related by birth, marriage, or adoption who live together.

Most HRSA programs use the income of a student's parent(s) to compute low-income status. However, a ''household'' may potentially be only one person. Other HRSA programs, depending upon the legislative intent of the program, the programmatic purpose related to income level, as well as the age and circumstances of the participant, will apply these low-income standards to the individual student to determine eligibility, if the student is not listed as a dependent on the tax form of their parent(s). Each program includes the rationale and methodology for determining low-income levels in program funding opportunities or applications.

Low-income levels are adjusted annually based on HHS's poverty guidelines. HHS's poverty guidelines are based on poverty thresholds published by the U.S. Census Bureau, adjusted annually for changes in the Consumer Price Index. The income figures below have been updated to reflect HHS's 2023 poverty guidelines as published in the **Federal Register** at 88 FR 3424. See *https://www.govinfo.gov/content/pkg/FR-2023-01-19/pdf/2023-00885.pdf.*