

CFR 314.510). PROAMATINE is indicated for the treatment of orthostatic hypotension. PROAMATINE (midodrine hydrochloride) tablets, 2.5 mg, 5 mg, and 10 mg, is currently listed in the “Discontinued Drug Product List” section of the Orange Book. Shire no longer markets PROAMATINE in any strength; although there are approved ANDAs referencing NDA 019815, PROAMATINE has been withdrawn from sale.

We have carefully reviewed our files for records concerning the withdrawal of PROAMATINE (midodrine hydrochloride) tablets, 2.5 mg, 5 mg, and 10 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. FDA has determined under § 314.161 that PROAMATINE (midodrine hydrochloride) tablets, 2.5 mg, 5 mg, and 10 mg, were not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, FDA will continue to list PROAMATINE (midodrine hydrochloride) tablets, 2.5 mg, 5 mg, and 10 mg, in the “Discontinued Drug Product List” section of the Orange Book. We note that, because PROAMATINE (midodrine hydrochloride) tablets, 2.5 mg, 5 mg, and 10 mg, were approved under the accelerated approval pathway, Shire was required to conduct post-approval studies to verify the clinical benefit of PROAMATINE (midodrine hydrochloride) tablets, 2.5 mg, 5 mg, and 10 mg. The clinical benefit of

PROAMATINE (midodrine hydrochloride) tablets, 2.5 mg, 5 mg, and 10 mg, remains subject to verification.

ANDAs that refer to PROAMATINE (midodrine hydrochloride) tablets, 2.5 mg, 5 mg, and 10 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: October 15, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–23014 Filed 10–21–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice To Announce Project Period Extensions With Funding for Health Center Program Award Recipients in Pago Pago, American Samoa; Bishop, California; Baltimore, Maryland; and Worcester, Massachusetts

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

ACTION: Notice.

SUMMARY: Additional grant funds were provided to four Health Center Program

award recipients with project periods ending in fiscal year (FY) 2019 to extend their project periods by up to four months to ensure the ongoing delivery of services until a new award could be made.

SUPPLEMENTARY INFORMATION:

Recipients of the Award: Four award recipients, as listed in Table 1, in Pago Pago, American Samoa; Bishop, California; Baltimore, Maryland; and Worcester, Massachusetts.

Amount of Non-Competitive Awards: \$3,066,387.

Period of Supplemental Funding: FY 2019.

Assistance Listings (CFDA) Number: 93.224.

Authority: Public Health Service Act, Section 330, as amended (42 U.S.C. 254b, as amended).

Justification: HRSA extended the FY 2019 project periods with prorated supplemental grant funds to four award recipients by up to four months until a new award is made for each service area. Continued funding to the Health Center Program award recipients ensured that individuals in the service areas received uninterrupted access to needed health care services. The approvals enabled HRSA to support consistent health care to beneficiaries, eliminate delays in funding gaps, and demonstrate administrative efficiencies. HRSA awarded approximately \$3 million to the four existing Health Center Program award recipients noted in Table 1.

TABLE 1—RECIPIENTS AND AWARD AMOUNTS

Grant No.	Award recipient name	City, state	Extension length (months)	Award amount
H80CS02470	American Samoa Government Department of Health.	Pago Pago, American Samoa	3	\$775,917
H80CS26629	Toiyabe Indian Health Project, Inc	Bishop, California	4	382,549
H80CS00067	Parkwest Health Systems, Inc	Baltimore, Maryland	4	1,326,373
H80CS00003	Community Healthlink, Inc	Worcester, Massachusetts	4	581,548

FOR FURTHER INFORMATION CONTACT: Olivia Shockey, Expansion Division Director, Office of Policy and Program Development, Bureau of Primary Health Care, Health Resources and Services Administration, at *oshockey@hrsa.gov* or 301–594–4300.

Dated: October 8, 2019.

Thomas J. Engels,

Acting Administrator.

[FR Doc. 2019–22984 Filed 10–21–19; 8:45 am]

BILLING CODE 4165–15–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 September 1, 2019, through September 30, 2019. 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, Healthcare 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.

Dated: October 11, 2019.

Thomas J. Engels,
Acting Administrator.

List of Petitions Filed

1. Dianna Heiner, McKinney, Texas, Court of Federal Claims No: 19-1339V
2. Phillip Shaak, Lancaster, Pennsylvania, Court of Federal Claims No: 19-1341V
3. Jonathan Ledee, Greenvale, New York, Court of Federal Claims No: 19-1342V
4. Renee Wyn, Dallas, Texas, Court of Federal Claims No: 19-1343V

5. Paul Eidsness, Excelsior, Minnesota, Court of Federal Claims No: 19-1344V
6. Jeffrey Warbritton, Tampa, Florida, Court of Federal Claims No: 19-1345V
7. Susan Coats, Greenville, South Carolina, Court of Federal Claims No: 19-1347V
8. Danae Plank, Charlotte, North Carolina, Court of Federal Claims No: 19-1350V
9. Shirley Worth Bodie, Gainesville, Florida, Court of Federal Claims No: 19-1351V
10. Andres DelReal, Waupun, Wisconsin, Court of Federal Claims No: 19-1352V
11. Mary Jones, Picayune, Mississippi, Court of Federal Claims No: 19-1355V
12. Aretta Diane James, Nutter Fort, West Virginia, Court of Federal Claims No: 19-1357V
13. Carmine Maiorano, Trevoese, Pennsylvania, Court of Federal Claims No: 19-1358V
14. Tamara A. Walker, Greensboro, North Carolina, Court of Federal Claims No: 19-1359V
15. Joanna Holle, Georgetown, Texas, Court of Federal Claims No: 19-1360V
16. Kevin Kelly, Washington, Michigan, Court of Federal Claims No: 19-1362V
17. Angela Hiatt, Ogden, Utah, Court of Federal Claims No: 19-1363V
18. Saeeda Syed, West Valley City, Utah, Court of Federal Claims No: 19-1364V
19. Susan Kaye Roselli, Corning, California, Court of Federal Claims No: 19-1365V
20. Sherrie Lewis, Durham, North Carolina, Court of Federal Claims No: 19-1369V
21. Kristin Kelley-Stanberry, Broken Arrow, Oklahoma, Court of Federal Claims No: 19-1371V
22. Karleen Witt, St. Paul, Minnesota, Court of Federal Claims No: 19-1372V
23. Ennetta Jeans, Gainesville, Virginia, Court of Federal Claims No: 19-1374V
24. Kim Boyer, Valencia, Pennsylvania, Court of Federal Claims No: 19-1377V
25. Lisa Spratt, Garden City, New York, Court of Federal Claims No: 19-1379V
26. Jennifer Joyce, Washington, District of Columbia, Court of Federal Claims No: 19-1380V
27. Megan Lynagh, New York, New York, Court of Federal Claims No: 19-1381V
28. Ira Shankar, Sugar Land, Texas, Court of Federal Claims No: 19-1382V
29. Dana Nelson, Sioux Falls, South Dakota, Court of Federal Claims No: 19-1383V
30. David Smith, Belmont, North Carolina, Court of Federal Claims No: 19-1384V
31. Dilip Thekkoodan, Cambridge, Massachusetts, Court of Federal Claims No: 19-1385V
32. Josephine Crowley, Staten Island, New York, Court of Federal Claims No: 19-1386V
33. Lisa Clark, Safety Harbor, Florida, Court of Federal Claims No: 19-1387V
34. Yenya Castillo, Boston, Massachusetts, Court of Federal Claims No: 19-1388V
35. Richard P. McKenna, Carmel, Indiana, Court of Federal Claims No: 19-1389V
36. Martha Sue Riley, Booneville, Kentucky, Court of Federal Claims No: 19-1392V
37. Linda Joy Davis, Fort Smith, Arkansas, Court of Federal Claims No: 19-1393V
38. Matthew Karp, Norwalk, Connecticut, Court of Federal Claims No: 19-1395V
39. Michele Mulloy, Duck, North Carolina,

- Court of Federal Claims No: 19-1396V
40. Catalina Sastre, New York, New York, Court of Federal Claims No: 19-1397V
41. Joanne Seivwright, Bolingbrook, Illinois, Court of Federal Claims No: 19-1398V
42. Claudia Collingnon-Harvath, Stockton, California, Court of Federal Claims No: 19-1399V
43. Mariann Bird, Orange Park, Florida, Court of Federal Claims No: 19-1400V
44. Renee Goree, Milwaukee, Wisconsin, Court of Federal Claims No: 19-1401V
45. Michelle Leatherman, Weatherford, Texas, Court of Federal Claims No: 19-1402V
46. Kevin Sarni on behalf of Audrey Hinojosa (Hernandez) Sarni, Oro Valley, Arizona, Court of Federal Claims No: 19-1403V
47. Ronald Davison on behalf of Estate of Gary Davison, North Chicago, Illinois, Court of Federal Claims No: 19-1404V
48. Joseph Filipovich, Cottage Grove, Minnesota, Court of Federal Claims No: 19-1406V
49. Roxanna Commanche, Farmington, New Mexico, Court of Federal Claims No: 19-1409V
50. Jennifer Lee Smith, Salt Lake City, Utah, Court of Federal Claims No: 19-1410V
51. Alaina Guymon, Seattle, Washington, Court of Federal Claims No: 19-1411V
52. Kathie Smith, Chevy Chase, Maryland, Court of Federal Claims No: 19-1412V
53. Tandy Thomas, McAlester, Oklahoma, Court of Federal Claims No: 19-1413V
54. Ellen Moss, Hudson, New York, Court of Federal Claims No: 19-1415V
55. Jeanette Peregoy, Dunkirk, Maryland, Court of Federal Claims No: 19-1416V
56. Jesus Garcia, Spring Hill, Florida, Court of Federal Claims No: 19-1418V
57. Eden Williams, Dresher, Pennsylvania, Court of Federal Claims No: 19-1420V
58. Darla Johnson, Greensboro, North Carolina, Court of Federal Claims No: 19-1422V
59. Kelly Bradley, Charlotte, North Carolina, Court of Federal Claims No: 19-1423V
60. Julia Simpson, Germantown, Tennessee, Court of Federal Claims No: 19-1424V
61. Antoinette Norris, Stuart, Florida, Court of Federal Claims No: 19-1425V
62. Sean Holtzclaw, Fort Wayne, Indiana, Court of Federal Claims No: 19-1426V
63. Kimberly Melhado, Huntington, New York, Court of Federal Claims No: 19-1427V
64. Lisa McGuire, Fountainville, Pennsylvania, Court of Federal Claims No: 19-1428V
65. Craig Pederson, San Antonio, Texas, Court of Federal Claims No: 19-1429V
66. Charles Kootsaes, Easton, Pennsylvania, Court of Federal Claims No: 19-1430V
67. Katherine D. Wham, Seattle, Washington, Court of Federal Claims No: 19-1431V
68. Amy Norton, Somerville, Massachusetts, Court of Federal Claims No: 19-1432V
69. Alexi Stoev, Lakewood Ranch, Florida, Court of Federal Claims No: 19-1433V
70. Brianna Zabek, Woodstock, Georgia, Court of Federal Claims No: 19-1434V
71. Ronald Adkins, Senatobia, Mississippi, Court of Federal Claims No: 19-1435V
72. Matthew Driggers, Tallahassee, Florida, Court of Federal Claims No: 19-1436V
73. Kenneth Lauria, Schaumburg, Illinois, Court of Federal Claims No: 19-1437V
74. Debra Blom, South Lyon, Michigan, Court of Federal Claims No: 19-1438V
75. Stacy Helton, Mt. Sterling, Kentucky, Court of Federal Claims No: 19-1440V
76. Benjamin Mynhier, Mt. Sterling, Kentucky, Court of Federal Claims No: 19-1441V
77. Michael G. McCarty, Mt. Sterling, Kentucky, Court of Federal Claims No: 19-1442V
78. John Thomas, Mt. Sterling, Kentucky, Court of Federal Claims No: 19-1443V
79. Richard Lykins, Mt. Sterling, Kentucky, Court of Federal Claims No: 19-1444V
80. Jeremy Adams, Mt. Sterling, Kentucky, Court of Federal Claims No: 19-1445V
81. Elaine Dimeo, Belmont, North Carolina, Court of Federal Claims No: 19-1447V
82. Kathleen Carlow, Albuquerque, New Mexico, Court of Federal Claims No: 19-1449V
83. Katherine Krietor, Phoenix, Arizona, Court of Federal Claims No: 19-1450V
84. Sabrina Compton and Wayne Compton on behalf of L.C., Crystal River, Florida, Court of Federal Claims No: 19-1455V
85. Kristinia Brooks, Greenville, South Carolina, Court of Federal Claims No: 19-1456V
86. Karen Conley, Santa Fe, New Mexico, Court of Federal Claims No: 19-1458V
87. Ernest Robirts on behalf of Estate of Harriet Robirts, Deceased, Jacksonville, Florida, Court of Federal Claims No: 19-1460V
88. Roy Levitt, Boston, Massachusetts, Court of Federal Claims No: 19-1461V
89. Joann Manzella, Boston, Massachusetts, Court of Federal Claims No: 19-1462V
90. Elizabeth Loughren, Cooperstown, New York, Court of Federal Claims No: 19-1463V
91. Joseph Crocker, Gainesville, Georgia, Court of Federal Claims No: 19-1465V
92. Mary Ann Jones, New Bern, North Carolina, Court of Federal Claims No: 19-1466V
93. Billy Beene, Russiaville, Indiana, Court of Federal Claims No: 19-1467V
94. Denise Wunderler and Michael Savino on behalf of V.C.S., Deceased, Louisville, Kentucky, Court of Federal Claims No: 19-1468V
95. William Forney, Severn, Maryland, Court of Federal Claims No: 19-1469V
96. Jeffrey Pritchett, Fargo, North Dakota, Court of Federal Claims No: 19-1470V
97. Tammy Kramer, Washington, District of Columbia, Court of Federal Claims No: 19-1471V
98. Dionne Spell, Wilson, North Carolina, Court of Federal Claims No: 19-1472V
99. Brandy Phipps, Warrensville, North Carolina, Court of Federal Claims No: 19-1473V
100. Michael Berge, Marshall, Virginia, Court of Federal Claims No: 19-1474V
101. Daniel Van Doren, Bay Pines, Florida, Court of Federal Claims No: 19-1475V
102. Deborah N. Coleman, Lynchburg, Virginia, Court of Federal Claims No: 19-1476V
103. Julie Pierantoni, Dripping Springs, Texas, Court of Federal Claims No: 19-1477V
104. Tony Riddell, Louisville, Kentucky, Court of Federal Claims No: 19-1479V
105. Shawna O'Brien, Sonora, California, Court of Federal Claims No: 19-1480V
106. Nikki Aune, Hibbing, Minnesota, Court of Federal Claims No: 19-1481V
107. George Stattner, Chicago, Illinois, Court of Federal Claims No: 19-1482V
108. Christa Beate Hamilton, Renton, Washington, Court of Federal Claims No: 19-1483V
109. Carl Haught, Hawley, Pennsylvania, Court of Federal Claims No: 19-1484V
110. Christine Rottino, Wayne, New Jersey, Court of Federal Claims No: 19-1485V
111. Yvonne Sewell, Clarence, New York, Court of Federal Claims No: 19-1486V
112. Donna Baxter, St. Petersburg, Florida, Court of Federal Claims No: 19-1488V
113. Marcelina Academia, San Diego, California, Court of Federal Claims No: 19-1490V
114. Brian Oberschmid and Heather Oberschmid on behalf of J.O., Woodbury, Minnesota, Court of Federal Claims No: 19-1491V
115. Yalawa Johnson, Boston, Massachusetts, Court of Federal Claims No: 19-1493V
116. Brad Yorgy and Rachel Yorgy on behalf of H.Y., Red Lion, Pennsylvania, Court of Federal Claims No: 19-1494V
117. Michelle McNabb, Columbus, Georgia, Court of Federal Claims No: 19-1495V
118. Brittany Bartlett, Marietta, Georgia, Court of Federal Claims No: 19-1500V
119. Anna Krupp, New York, New York, Court of Federal Claims No: 19-1501V
120. Tiffany Hale, Marion, Illinois, Court of Federal Claims No: 19-1502V
121. Doris Lamberton, Sebring, Florida, Court of Federal Claims No: 19-1504V
122. Maija Harkonen, Washington, District of Columbia, Court of Federal Claims No: 19-1505V
123. Jessica Bechhofer, Boston, Massachusetts, Court of Federal Claims No: 19-1506V
124. Elizabeth Hurlbutt, Asheville, North Carolina, Court of Federal Claims No: 19-1507V
125. Brian Davis, Elizabethtown, Pennsylvania, Court of Federal Claims No: 19-1508V
126. Barbara Gill, Murrieta, California, Court of Federal Claims No: 19-1509V
127. Leo Damon, Jr., Baltimore, Maryland, Court of Federal Claims No: 19-1510V
128. William Elias, Pittsfield, Massachusetts, Court of Federal Claims No: 19-1512V
129. Barry Taylor, Dallas, Texas, Court of Federal Claims No: 19-1513V