

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹—Continued

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
111.570, Records regarding product complaints	240	600	144,000	0.5 (30 minutes)	72,000
Total					929,140

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

The average burden per recordkeeping estimates in Table 1 of this document are based on those in the June 25, 2007, final rule, which were based on our institutional experience with other CGMP requirements and on data provided by Research Triangle Institute in the “Survey of Manufacturing Practices in the Dietary Supplement Industry” cited in that rule.

The estimates in table 1 of the number of firms affected by each provision of part 111 are based on the percentage of manufacturers, packagers, labelers, holders, distributors, and warehouseers that reported in the survey that they have not established written SOPs or do not maintain records that were later required by the June 25, 2007, final rule. Because we do not have survey results for general warehouses, we entered the approximate number of facilities in that category for those provisions covering general facilities. For the dietary supplement industry, the survey estimated that 1,460 firms would be covered by the final rule, including manufacturers, packagers, labelers, holders, distributors, and warehouseers. The time estimates include the burden involved in documenting that certain requirements are performed and in recordkeeping. We used an estimated annual batch production of 1,408 batches per year to estimate the burden of requirements that are related to the number of batches produced annually, such as § 111.260, “What must the batch production record include?” The estimate of 1,408 batches per year is near the midpoint of the number of annual batches reported by survey firms.

The length of time that CGMP records must be maintained is set forth in § 111.605. Table 1 of this document reflects the estimated burdens for written procedures, record maintenance, periodically reviewing records to determine if they may be discarded, and for any associated documentation for that activity for records that are required under part 111. We have not included a separate estimate of burden for those sections that require maintaining records in accordance with § 111.605, but have included those burdens under

specific provisions for keeping records. For example, § 111.255(a) requires that the batch production records be prepared every time a batch is manufactured, and § 111.255(d) requires that batch production records be kept in accordance with § 111.605. The estimated burdens for both § 111.255(a) and (d) are included under § 111.260, what the batch record must include.

Dated: September 23, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–23521 Filed 9–28–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–3326]

Biosimilar User Fee Act; Public Meeting; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration is correcting a notice entitled “Biosimilar User Fee Act; Public Meeting” that appeared in the **Federal Register** of September 19, 2016 (81 FR 64171). The document announced a public meeting to discuss proposed recommendations for the reauthorization of the Biosimilar User Fee Act (BsUFA) for fiscal years (FYs) 2018 through 2022. The document was published with the incorrect date of the closure of the docket and incorrect transcript information. This document corrects those errors.

FOR FURTHER INFORMATION CONTACT: Lisa Granger, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3330, Silver Spring, MD 20993–0002, 301–796–9115, lisa.granger@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Monday, September 19, 2016, in FR Doc. 2016–22442, the following corrections are made:

1. On page 64172, in the first column, in the third sentence of the **DATES**

section, “October 19, 2016” is corrected to read “October 28, 2016.”

2. On page 64175, in the third column, the section “*Transcripts:* As soon as a transcript is available, FDA will post it at <http://www.fda.gov/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/ucm461774.htm>.” is corrected to read “*Transcripts:* Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov> and <http://www.fda.gov/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/ucm461774.htm>. It may be viewed at the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency’s Web site at <http://www.fda.gov>.”

Dated: September 23, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–23523 Filed 9–28–16; 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 Section 2112(b)(2) of the Public Health Service (PHS) Act, as amended. While the Secretary of HHS (the Secretary) 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 the Clerk, 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, MD 20857; (301) 443-6593, or visit our Web site 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 U.S. Court of Federal Claims and serve a copy of the petition on the Secretary of Health and Human Services, 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 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 August 1, 2016, through August 31, 2016. 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 U.S. 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, MD 20857. The Court's caption (Petitioner's Name v. Secretary of Health and Human Services) 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: September 22, 2016.

James Macrae,
Acting Administrator.

List of Petitions Filed

1. Victoria Cohen, Norwood, Massachusetts, Court of Federal Claims No: 16-0910V.
2. Cheryl Stephens, Portland, Texas, Court of Federal Claims No: 16-0913V.
3. John Greider, Plano, Texas, Court of

- Federal Claims No: 16-0915V.
4. Jessie M. Holloway, Houston, Texas, Court of Federal Claims No: 16-0919V.
5. Stephanie Digerolamo, Cedar Brook, New Jersey, Court of Federal Claims No: 16-0920V.
6. Melinda Holgate, Syracuse, New York, Court of Federal Claims No: 16-0921V.
7. Michele Baxter on behalf of L.R., Fayetteville, Tennessee, Court of Federal Claims No: 16-0922V.
8. Stephanie Nwala and Emmanuel Nwala on behalf of C.N., Aberdeen, South Dakota, Court of Federal Claims No: 16-0923V.
9. Susan Cobbina, Spencerport, New York, Court of Federal Claims No: 16-0924V.
10. Patrice Moczek on behalf of K.H., Shadyside, Ohio, Court of Federal Claims No: 16-0930V.
11. Wanda Hughs on behalf of A.E.H., Meridian, Mississippi, Court of Federal Claims No: 16-0934V.
12. Michael Anderson and Hasani Taylor on behalf of K.A., Valhalla, New York, Court of Federal Claims No: 16-0935V.
13. George M. Gavin, Pittsburgh, Pennsylvania, Court of Federal Claims No: 16-0936V.
14. Greg Averitt, Perryton, Texas, Court of Federal Claims No: 16-0938V.
15. William Lance Ferguson, Corpus Christi, Texas, Court of Federal Claims No: 16-0939V.
16. Paulette Stuart, Valley Stream, New York, Court of Federal Claims No: 16-0940V.
17. Danny Pasawongse and Kristy M. Suh on behalf of I.Y.P., San Mateo, California, Court of Federal Claims No: 16-0944V.
18. Armicka S. Miller on behalf of The Estate of Arnold Lee Miller, Deceased, Hampton, Virginia, Court of Federal Claims No: 16-0946V.
19. Peter Matte, Houston, Texas, Court of Federal Claims No: 16-0949V.
20. Helga Matthews, Glendale, Arizona, Court of Federal Claims No: 16-0951V.
21. Melissa Bianconi on behalf of S.L., Seattle, Washington, Court of Federal Claims No: 16-0952V.
22. Donald Jackson, Lexington, Kentucky, Court of Federal Claims No: 16-0955V.
23. Leonard Sean Thompson, Hoboken, New Jersey, Court of Federal Claims No: 16-0956V.
24. Flora Adler, Russiaville, Indiana, Court of Federal Claims No: 16-0960V.
25. Marilyn Smith, Dallas, Texas, Court of Federal Claims No: 16-0961V.
26. Niki Delson, Saugerties, New York, Court of Federal Claims No: 16-0962V.
27. Barbara Sease, Chambersburg, Pennsylvania, Court of Federal Claims No: 16-0964V.
28. David Fenster, Princeton, New Jersey, Court of Federal Claims No: 16-0965V.
29. Tamara Frye, Topeka, Kansas, Court of Federal Claims No: 16-0966V.
30. Horace Mungin, Goose Creek, South Carolina, Court of Federal Claims No: 16-0968V.
31. Ann Meril, Yonkers, New York, Court of Federal Claims No: 16-0969V.
32. Abdolrahim Noorani, Levittown, Pennsylvania, Court of Federal Claims No: 16-0970V.
33. William Dye, Portland, Maine, Court of

- Federal Claims No: 16–0971V.
34. Donnie Jordan, Springfield, Virginia, Court of Federal Claims No: 16–0972V.
 35. David Davis, Lumberton, North Carolina, Court of Federal Claims No: 16–0974V.
 36. Mary Germano, Washington, District of Columbia, Court of Federal Claims No: 16–0976V.
 37. David Hanson, New Hope, Minnesota, Court of Federal Claims No: 16–0977V.
 38. Kathleen A. Seko, Kitty Hawk, North Carolina, Court of Federal Claims No: 16–0978V.
 39. Jacklyn Hallead, Bay City, Michigan, Court of Federal Claims No: 16–0979V.
 40. Jean Gentile, Saint Louis Park, Minnesota, Court of Federal Claims No: 16–0980V.
 41. Pam Mecagni, Collinsville, Illinois, Court of Federal Claims No: 16–0981V.
 42. Sara Faley, Dixon, Illinois, Court of Federal Claims No: 16–0982V.
 43. Brady Scott, Westminster, Colorado, Court of Federal Claims No: 16–0983V.
 44. Linda Multer, Somerville, Massachusetts, Court of Federal Claims No: 16–0985V.
 45. Rhonda Larson, Woodbridge, Virginia, Court of Federal Claims No: 16–0986V.
 46. Holly Dlouhy, Houston, Texas, Court of Federal Claims No: 16–0987V.
 47. Kimberly Daniel, New York, New York, Court of Federal Claims No: 16–0988V.
 48. Kameshwar Rao S. Ayyasolla, Lake Success, New York, Court of Federal Claims No: 16–0989V.
 49. Paul Schachter, Fort Wright, Kentucky, Court of Federal Claims No: 16–0990V.
 50. Denise Procida, Atlanta, Georgia, Court of Federal Claims No: 16–0991V.
 51. Nicola Winkel, Phoenix, Arizona, Court of Federal Claims No: 16–0992V.
 52. Gary Hausdorf, Minneapolis, Minnesota, Court of Federal Claims No: 16–0993V.
 53. Nicholas Zumwalt on behalf of L.Z., Broken Arrow, Oklahoma, Court of Federal Claims No: 16–0994V.
 54. Marie Campbell on behalf of Andrew J. Campbell, Whippany, New Jersey, Court of Federal Claims No: 16–0996V.
 55. Anna Perekotiy on behalf of S.K., Scottsdale, Arizona, Court of Federal Claims No: 16–0997V.
 56. Artha Timothy, Hope Mills, North Carolina, Court of Federal Claims No: 16–0998V.
 57. Donald Butts, Jr., Middletown, Ohio, Court of Federal Claims No: 16–1002V.
 58. Gerald Sather, Port Orchard, Washington, Court of Federal Claims No: 16–1004V.
 59. Peter A. Voss, Menomonee Falls, Wisconsin, Court of Federal Claims No: 16–1005V.
 60. Jane Rocha-DeMelo, Swansea, Massachusetts, Court of Federal Claims No: 16–1007V.
 61. Mee Lee on behalf of Maiyer Lee, Milwaukee, Wisconsin, Court of Federal Claims No: 16–1008V.
 62. Fred Booth, Birmingham, Alabama, Court of Federal Claims No: 16–1012V.
 63. Patrick C. Richardson, Waianae, Hawaii, Court of Federal Claims No: 16–1013V.
 64. Anita Romero, Huntington Valley, Pennsylvania, Court of Federal Claims No: 16–1014V.
 65. Daniel Soper, Boston, Massachusetts, Court of Federal Claims No: 16–1016V.
 66. Norman Larsen, Staten Island, New York, Court of Federal Claims No: 16–1018V.
 67. Valerie Silver on behalf of R.S., Nyak, New York, Court of Federal Claims No: 16–1019V.
 68. Michael Rochotte, New Brunswick, New Jersey, Court of Federal Claims No: 16–1024V.
 69. Mark P. Calnan, Lexington, Massachusetts, Court of Federal Claims No: 16–1025V.
 70. John Belt, Lakewood, Colorado, Court of Federal Claims No: 16–1026V.
 71. Crystal Butler on behalf of S.B., Phoenix, Arizona, Court of Federal Claims No: 16–1027V.
 72. Turmak Davis, Wilmington, North Carolina, Court of Federal Claims No: 16–1028V.
 73. Daniel McNeal, Indianapolis, Indiana, Court of Federal Claims No: 16–1029V.
 74. Jessica Roberts, Woodbury, Minnesota, Court of Federal Claims No: 16–1030V.
 75. Beverly Massey, Sister Bay, Wisconsin, Court of Federal Claims No: 16–1032V.
 76. Sharlee Funai, Honolulu, Hawaii, Court of Federal Claims No: 16–1033V.
 77. Alexis Obers, Solvang, California, Court of Federal Claims No: 16–1034V.
 78. Regina O. Fletcher, Nesconset, New York, Court of Federal Claims No: 16–1037V.
 79. Deborah Chrowl, Salem, Oregon, Court of Federal Claims No: 16–1040V.
 80. Michael Bates, Rock Hill, South Carolina, Court of Federal Claims No: 16–1041V.
 81. Brandon Hood, Kingwood, Texas, Court of Federal Claims No: 16–1042V.
 82. Lanesia Shea on behalf of A.S., Las Cruces, New Mexico, Court of Federal Claims No: 16–1043V.
 83. Aprises Phillips and Ivan Phillips, Sr. on behalf of Ivana Phillips, Birmingham, Alabama, Court of Federal Claims No: 16–1044V.
 84. Aprises Phillips and Ivan Phillips, Sr. on behalf of Ivana Phillips, Birmingham, Alabama, Court of Federal Claims No: 16–1045V.
 85. Aprises Phillips and Ivan Phillips, Sr. on behalf of Ivan Phillips, Birmingham, Alabama, Court of Federal Claims No: 16–1046V.
 86. Ursula Rehfeld, Berlin, Germany, Court of Federal Claims No: 16–1048V.
 87. Kelsey Hanstead, Mt. Vernon, Washington, Court of Federal Claims No: 16–1050V.
 88. Shannon Jablonski, Washington, District of Columbia, Court of Federal Claims No: 16–1051V.
 89. Fabrizio Cianni on behalf of Carmella Cianni, Deceased, Vienna, Virginia, Court of Federal Claims No: 16–1052V.
 90. James Lagle, Huntingdon, Pennsylvania, Court of Federal Claims No: 16–1053V.
 91. Diana Malick, Swarthmore, Pennsylvania, Court of Federal Claims No: 16–1054V.
 92. Rachel McCarron, Groton, Massachusetts, Court of Federal Claims No: 16–1055V.
 93. Robert Manuel, Bakersfield, California, Court of Federal Claims No: 16–1057V.
 94. Luis Trigueros, Boston, Massachusetts, Court of Federal Claims No: 16–1058V.
 95. Linda Hubbard on behalf of Leslie McKnight, Deceased, Boulder, Colorado, Court of Federal Claims No: 16–1059V.
 96. Jenifer Twiford, San Francisco, California, Court of Federal Claims No: 16–1060V.
 97. William Staak, Jr., Jonesboro, Georgia, Court of Federal Claims No: 16–1061V.
 98. Claydene Benson, Beverly Hills, California, Court of Federal Claims No: 16–1062V.
 99. Kim Manget, Beverly Hills, California, Court of Federal Claims No: 16–1064V.
 100. John Strowger, Largo, Florida, Court of Federal Claims No: 16–1065V.
 101. Vickie L. Dern on behalf of David J. Dern, Deceased, Birmingham, Alabama, Court of Federal Claims No: 16–1066V.
 102. Kim LaFountaine, Longview, Washington, Court of Federal Claims No: 16–1067V.
 103. Linda Hagans, Villa Rica, Georgia, Court of Federal Claims No: 16–1068V.
 104. George Easton, Hazelton, Pennsylvania, Court of Federal Claims No: 16–1069V.
 105. Cathy Deshler, Salt Lake City, Utah, Court of Federal Claims No: 16–1070V.
 106. Ala Mohamad, Denver, Colorado, Court of Federal Claims No: 16–1075V.
 107. Bonnie Stratton, Brea, California, Court of Federal Claims No: 16–1076V.
 108. Minh Le, Bristol, Pennsylvania, Court of Federal Claims No: 16–1078V.
 109. Jean de Bary, Boston, Massachusetts, Court of Federal Claims No: 16–1080V.
 110. Chiyoko Miller, Washington, District of Columbia, Court of Federal Claims No: 16–1081V.
 111. Jeffrey Heise and Meghan Heise on behalf of L.D.H., Wausau, Wisconsin, Court of Federal Claims No: 16–1082V.
 112. Julia Sullivan, Phoenix, Arizona, Court of Federal Claims No: 16–1083V.
 113. Richard Waters, Phoenix, Arizona, Court of Federal Claims No: 16–1084V.
 114. Carol Katora, York, Pennsylvania, Court of Federal Claims No: 16–1086V.
 115. Teresa Shuart, Syracuse, New York, Court of Federal Claims No: 16–1087V.
 116. Pauline Zand, Greenbrae, California, Court of Federal Claims No: 16–1088V.
 117. Heather Sturtze, Worcester, Massachusetts, Court of Federal Claims No: 16–1089V.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Announcement of Requirements and Registration for “The Simple Extensible Sampling Tool Challenge”

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice.

SUMMARY: The Simple Extensible Sampling Tool Challenge (Challenge) is an HHS/OIG Challenge under the “America COMPETES” (Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science) Reauthorization Act of