arrange for scheduling and participation as appropriate.

Similarly, the guidance explains and discusses the preparation of an ''information package'' and recommends that it include the following information:

- Identifying information about the underlying product;
- a brief statement of the purpose of the meeting; a list of objectives and expected outcomes of the meeting;
- a proposed agenda for the meeting;
- a list of specific questions to be addressed at the meeting;
- a summary of clinical data that will be discussed (as appropriate);
- a summary of preclinical data that will be discussed (as appropriate); and
- chemistry, manufacturing, and controls information that may be discussed (as appropriate).

The information package enables us to prepare for the meeting and allows appropriate time for reviewing relevant product data. Although FDA reviews similar information in the meeting request, the information package should provide updated data reflecting the most current and accurate information available to the sponsor or applicant.

In the **Federal Register** of July 11, 2018 (83 FR 32130) we published a 60-day notice under the Paperwork Reduction Act of 1995 (PRA) requesting public comment on the proposed collection of information associated with meeting requests under PDUFA. No comments were received in response to the PRA notice. Separately, in the **Federal Register** (December 29, 2017; 82 FR 61763), we published a notice of availability announcing a 2017 revised draft version of the subject guidance, ultimately intending it to replace the current 2009 version. In the December 2017 notice of availability, the 2009 version was inadvertently withdrawn and the associated information collection discontinued. Accordingly, we are requesting reinstatement of the information collection. Although the associated guidance is currently being revised to reflect 2018–2022 PDUFA reauthorization goals and is being issued consistent with our Good Guidance Practice Regulation at 21 CFR 10.115, no changes have been made to the information collection elements recommended, nor have we modified the burden estimate we ascribe to the related activities.

We therefore estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Guidance recommendations	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Meeting Requests:					
CDER	1,319	2.31	3,058	10	30,580
CBER	301	1.21	363	10	3,630
Subtotal					34,210
Information Packages:					
CDER	1,149	2.19	2,522	18	45,396
CBER	187	1.12	210	18	3,780
Subtotal					49,176
Total					83,386

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

Our estimate reflects an overall increase since the previous OMB approval. We attribute this adjustment to an increase in the number of PDUFA-related meeting requests and information packages we have received over the last few years.

Based on Agency data, we estimate 1,319 sponsors and applicants (respondents) request 3,058 formal meetings with CDER annually, and 301 respondents request 363 formal meetings with CBER annually regarding the development and review of a PDUFA product. The hours per response, which is the estimated number of hours that a respondent spends preparing the information to be submitted with a meeting request in accordance with the guidance, is estimated to be 10 hours. We expect it takes this amount of time to gather and copy brief statements about the product as well as a description of the purpose and details of the meeting.

Also consistent with Agency data, we estimate 1,149 respondents submitted 2,522 information packages to CDER annually, and 187 respondents submitted 210 information packages to CBER annually, prior to a formal meeting regarding the development and review of a PDUFA product. We estimate 18 hours is needed to prepare the information package in accordance with the guidance.

Dated: December 10, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–27835 Filed 12–26–19; 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 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 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 November 1, 2019, through November 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: December 19, 2019.

Thomas J. Engels,

Administrator.

List of Petitions Filed

1. Christine Murschel, Coon Rapids, Minnesota, Court of Federal Claims No: 19–1700V
2. Colleen Hietpas on behalf of C. H., Neenah, Wisconsin, Court of Federal Claims No: 19–1702V
3. Fidencio Velasquez, Eagle Pass, Texas, Court of Federal Claims No: 19–1703V
4. Brooke Biel, West View, Pennsylvania, Court of Federal Claims No: 19–1704V
5. Joshua Brown, Bloomington, Indiana, Court of Federal Claims No: 19–1705V
6. Emily Thompson, Rocky Mount, North Carolina, Court of Federal Claims No: 19–1708V
7. Angela Lee, Kyle, Texas, Court of Federal Claims No: 19–1709V
8. Francisco Castellanos, Miami, Florida, Court of Federal Claims No: 19–1710V
9. Kenneth Holmes, Irving, Texas, Court of Federal Claims No: 19–1711V
10. Jaime Lehman, Miami, Florida, Court of Federal Claims No: 19–1712V
11. Mary Maloney, Stuart, Florida, Court of Federal Claims No: 19–1713V
12. Uriel Zamora and Edna Frias on behalf of A. Z., McAllen, Texas, Court of Federal Claims No: 19–1718V
13. Elizabeth Jackson, Boston, Massachusetts, Court of Federal Claims No: 19–1721V
14. Rose Dworkis, Glen Rock, New Jersey, Court of Federal Claims No: 19–1722V
15. Joanna Farjaszewska on behalf of A. M., Surprise, Arizona, Court of Federal Claims No: 19–1723V
16. Stephanie Stomel, Cherry Hill, New Jersey, Court of Federal Claims No: 19–1726V
17. Todd L. Friberg, Greensboro, North Carolina, Court of Federal Claims No: 19–1727V
18. Genevieve Avila, Waukegan, Illinois, Court of Federal Claims No: 19–1728V
19. Bobby Tate, Waupun, Wisconsin, Court of Federal Claims No: 19–1731V
20. Richard Porpora, Glen Falls, New York, Court of Federal Claims No: 19–1732V
21. Trina Garcia, Sparks, Nevada, Court of Federal Claims No: 19–1733V
22. Renee Worthy, Tallahassee, Florida, Court of Federal Claims No: 19–1735V
23. Henrietta LaRue, Lansdowne, Pennsylvania, Court of Federal Claims No: 19–1739V
24. Jonathan Cohen and Jessica Cohen on behalf of S. C., Deceased, Charlotte, North Carolina, Court of Federal Claims No: 19–1740V
25. Michelle Breslin, San Jose, California, Court of Federal Claims No: 19–1743V
26. Gary J. Hudeck, Midland, Michigan, Court of Federal Claims No: 19–1744V
27. Michael Eiras, Rocklin, California, Court of Federal Claims No: 19–1746V
28. Courtney Nina and Pedro Nina on behalf of Kennedy Nina, Odessa, Florida, Court of Federal Claims No: 19–1750V
29. Nancy Buzzelli Lilley, Greenville, North Carolina, Court of Federal Claims No: 19–1751V
30. Jason Manus, Englewood, New Jersey, Court of Federal Claims No: 19–1753V
31. Victoria Martinez, Wesley Chapel, Florida, Court of Federal Claims No: 19–1754V
32. Marlene Boger, Garrett, Indiana, Court of Federal Claims No: 19–1755V
33. Debra Owens, Beech Island, South Carolina, Court of Federal Claims No: 19–1757V
34. Esther Rubinson, Jackson, New Jersey,

Court of Federal Claims No: 19–1759V
35. Nicole Abrams-Kelly, Huntersville, North Carolina, Court of Federal Claims No: 19–1760V
36. Brittany Dock on behalf of K. E., Aurora, Colorado, Court of Federal Claims No: 19–1762V
37. Thomas Joseph Grandinetti, Syracuse, New York, Court of Federal Claims No: 19–1763V
38. Catherine Doyle, Cedar Knolls, New Jersey, Court of Federal Claims No: 19–1767V
39. Kristi A. Baker, Huntington, West Virginia, Court of Federal Claims No: 19–1771V
40. Olga Capkeviciene, Lakewood, Ohio, Court of Federal Claims No: 19–1773V
41. Laura Bell Frey, Franklin, Tennessee, Court of Federal Claims No: 19–1776V
42. Morgan Gaffney, Washington, District of Columbia, Court of Federal Claims No: 19–1777V
43. Katherine Beltz, Huntersville, North Carolina, Court of Federal Claims No: 19–1779V
44. Lisa B. Vendiola, Waipahu, Hawaii, Court of Federal Claims No: 19–1780V
45. Lisa J. Prince, Plano, Texas, Court of Federal Claims No: 19–1781V
46. Noelle Lynn Czopek on behalf of C. L. H., Jr., Pittsburgh, Pennsylvania, Court of Federal Claims No: 19–1782V
47. Ann M. Arpino, New Haven, Connecticut, Court of Federal Claims No: 19–1783V
48. Edwin Weiss, New York, New York, Court of Federal Claims No: 19–1786V
49. Julie Schottler, Rochester, Minnesota, Court of Federal Claims No: 19–1787V
50. Laura Valentin Maalouf, West Chester, Pennsylvania, Court of Federal Claims No: 19–1788V
51. Randy Li, Fort Polk, Louisiana, Court of Federal Claims No: 19–1789V
52. Donna Faye McKenney, Clackamas, Oregon, Court of Federal Claims No: 19–1799V
53. Phillip Woods, Novi, Michigan, Court of Federal Claims No: 19–1800V
54. Geoffrey Clive, Kansas City, Missouri, Court of Federal Claims No: 19–1802V
55. Connie Suzann Mundinger, Columbia, South Carolina, Court of Federal Claims No: 19–1804V
56. Carl Johnson, Eagan, Minnesota, Court of Federal Claims No: 19–1807V
57. Marjorie DeCamara, Manheim, Pennsylvania, Court of Federal Claims No: 19–1808V
58. Michelle Celentano, Tucson, Arizona, Court of Federal Claims No: 19–1809V
59. Claudia Marquez, Washington, District of Columbia, Court of Federal Claims No: 19–1811V
60. Thomas Bakker, Scottsdale, Arizona, Court of Federal Claims No: 19–1814V
61. Leigh-Anne Garry on behalf of M. G., Flourtown, Pennsylvania, Court of Federal Claims No: 19–1815V
62. Maria Reiser Manwill, West Valley City, Utah, Court of Federal Claims No: 19–1818V
63. Lori Hoeffken, Richmond, Texas, Court of Federal Claims No: 19–1819V
64. Tyler Ramdhanie, Halethorpe, Maryland, Court of Federal Claims No: 19–1820V
65. Misty Gehrke, Vancouver, Washington, Court of Federal Claims No: 19–1821V
66. Joyce C. Briggs, Durham, North Carolina, Court of Federal Claims No: 19–1822V
67. Michael Dean Vucenic, Modesto, California, Court of Federal Claims No: 19–1824V
68. Melissa Fischer, Clawson, Michigan, Court of Federal Claims No: 19–1825V

[FR Doc. 2019–27963 Filed 12–26–19; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Health Center Program Forms, OMB No. 0915–0285—Revision

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

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30 day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than January 27, 2020.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Health Center Program Forms OMB No. 0915–0285—Revision.

Abstract: The Health Center Program, administered by HRSA, is authorized under section 330 of the Public Health Service (PHS) Act, most recently amended by section 50901(b) of the Bipartisan Budget Act of 2018, Public Law 115–123. Health centers are community-based and patient-directed organizations that deliver affordable, accessible, quality, and cost-effective primary health care services to patients regardless of their ability to pay. Nearly 1,400 health centers operate approximately 12,000 service delivery sites that provide primary health care to more than 27 million people in every U.S. state, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and the Pacific Basin. HRSA utilizes forms for new and existing health centers and other entities to apply for various grant and non-grant opportunities, renew grant and non-grant designations, report progress, and change their scopes of project.

A 60-day notice was published in the **Federal Register** on April 8, 2019, vol. 84, No. 67; pp. 13937–38. No public comments were received.

Need and Proposed Use of the Information: Health Center Program-specific forms are necessary for Health Center Program award processes and oversight. These forms provide HRSA staff and objective review committee panels with information essential for application evaluation, funding recommendation and approval, designation, and monitoring. These forms also provide HRSA staff with information essential for evaluating compliance with Health Center Program legislative and regulatory requirements.

HRSA intends to make several changes to its forms:

- *HRSA will modify the following forms to streamline and clarify data (e.g., text changes, updated instructions) currently being collected:* 1A, 1B, 1C, 2, 3, 3A, 4, 5A, 5B, 5C, 6A, 8, 12, Checklist for Adding a New Service, Checklist for Adding a New Service Delivery Site, Checklist for Adding a New Target Population, Checklist for Deleting Existing Service, Checklist for Deleting Existing Service Delivery Site, Clinical Performance Measures, Equipment List, Expanded Services, Federal Object Class Categories, Financial Performance Measures, Funding Sources, Health Center Controlled Networks (HCCN) Progress Report Table, Operational Plan, Program Specific Forms Instructions, Project Qualification Criteria, Project Work Plan, Proposal Cover Page, and the Summary Page.
- *HRSA will rename the following forms:* Substance Abuse Progress Report will be changed to Health Center Program Progress Report, Program Narrative Update will be changed to Project Narrative Update, and Outreach and Enrollment Supplemental form will be changed to Health Center Program: Supplemental Information.