

to be used in conjunction with other FDA guidance documents, including device-specific guidances, as well as in conjunction with specific test reporting recommendations in FDA-recognized standards.

FDA considered comments received on the draft guidance that appeared in the **Federal Register** of May 31, 2018 (83 FR 25014). FDA revised the guidance as appropriate in response to the comments.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on recommended content and format of non-clinical bench performance testing information in premarket submissions. It does not

establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. This guidance document is also available at <https://www.regulations.gov>. Persons unable to download an electronic copy of "Recommended Content and Format

of Non-Clinical Bench Performance Testing Information in Premarket Submissions" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 18011 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

21 CFR part; guidance; or FDA form	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Device Exemption	0910–0332
812	Investigational Device Exemption	0910–0078
"De Novo Classification Process (Evaluation of Automatic Class III Designation)" ...	De Novo classification process	0910–0844

Dated: April 23, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–08466 Filed 4–25–19; 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 the Public Health Service (PHS) Act. While the Secretary of Health and Human Services 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, MD 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 U.S. Court of Federal Claims and to serve a copy of the petition on 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 March 1, 2019, through March 31, 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 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 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: April 22, 2019.

George Sigounas,
Administrator.

List of Petitions Filed

- Robert Kleinknecht, Naples, Florida, Court of Federal Claims No: 19–0325V
- David Pavish, Friendswood, Texas, Court of Federal Claims No: 19–0326V
- Mengyao Hu, Boston, Massachusetts, Court of Federal Claims No: 19–0327V
- Robert Vasquez, Fresno, California, Court of Federal Claims No: 19–0328V
- Richard G. Doble, Brewer, Maine, Court of Federal Claims No: 19–0335V
- Colleen Garten, Dunedin, Florida, Court of Federal Claims No: 19–0336V
- Isaac Friedman, Jacksonville, Florida, Court of Federal Claims No: 19–0337V
- Claretta Edwards, Oak Park, Illinois, Court of Federal Claims No: 19–0338V
- Susan Cheney, Encinitas, California, Court of Federal Claims No: 19–0341V
- Mong Ha Vivian Cheung, San Mateo, California, Court of Federal Claims No: 19–0342V
- Pamela Vibbard, Olympia, Washington, Court of Federal Claims No: 19–0343V
- Ivie Dotson on behalf of A.D., Cedar City, Utah, Court of Federal Claims No: 19–0344V
- Susanna Edelstein, Glenview, Illinois, Court of Federal Claims No: 19–0345V
- Cynthia Rublaitus, Alton, Illinois, Court of Federal Claims No: 19–0346V
- Doreen E. Beer, Roanoke, Virginia, Court of Federal Claims No: 19–0348V
- David McBane on behalf of R.M., Portland, Oregon, Court of Federal Claims No: 19–0350V
- Elizabeth Levine, Denville, New Jersey, Court of Federal Claims No: 19–0351V
- Ryan Faust, Boston, Massachusetts, Court of Federal Claims No: 19–0354V
- Kurt T. Westerlund, Pittsburgh, Pennsylvania, Court of Federal Claims No: 19–0355V
- Patrick Hansen, Mankato, Minnesota, Court of Federal Claims No: 19–0356V
- Daniel McAvoy, Chandler, Arizona, Court of Federal Claims No: 19–0357V
- Eileen Rescheske, Oshkosh, Wisconsin, Court of Federal Claims No: 19–0359V
- Susan Leone, White Plains, New York, Court of Federal Claims No: 19–0360V
- Megan Murphy Jones, Washington, District of Columbia, Court of Federal Claims No: 19–0361V
- Karla Strand, Washington, District of Columbia, Court of Federal Claims No: 19–0362V
- Jennifer Thompson, Charlottesville, Virginia, Court of Federal Claims No: 19–0363V
- Crystal Mertins, Dallas, Texas, Court of Federal Claims No: 19–0364V
- Rozene K. Whitaker-Jones, Canton, Georgia, Court of Federal Claims No: 19–0365V
- Gerald Hines, Wilsonville, Oregon, Court of Federal Claims No: 19–0366V
- Naila Hanif, Westbury, New York, Court of Federal Claims No: 19–0367V
- Melissa Strait, Windsor, Wisconsin, Court of Federal Claims No: 19–0368V
- Lorraine Fleagle, Philadelphia, Pennsylvania, Court of Federal Claims No: 19–0370V
- Amy Redford, Tampa, Florida, Court of Federal Claims No: 19–0375V
- Carol Gordon, Houston, Texas, Court of Federal Claims No: 19–0378V
- Erica Winebrenner on behalf of S.W., Deceased, Crossville, Tennessee, Court of Federal Claims No: 19–0379V
- Tom Janus and Beata Walerych Janus on behalf of M.J., Mineola, New York, Court of Federal Claims No: 19–0380V
- Aaron Scott, Waupun, Wisconsin, Court of Federal Claims No: 19–0381V
- Michael Terry, Douglasville, Georgia, Court of Federal Claims No: 19–0382V
- Marilyn Dixon Hill, Runnemede, New Jersey, Court of Federal Claims No: 19–0384V
- Tina Murry, Shoreline, Washington, Court of Federal Claims No: 19–0385V
- Diane R. Hecht, Webster, New York, Court of Federal Claims No: 19–0387V
- Mercedes Gallagher, San Diego, California, Court of Federal Claims No: 19–0389V
- Paula Roberts, Atlanta, Georgia, Court of Federal Claims No: 19–0390V
- Sue Decoretz, San Antonio, Texas, Court of Federal Claims No: 19–0391V
- Ann Furman, Kelso, Washington, Court of Federal Claims No: 19–0392V
- Charles Bracewell, Boston, Massachusetts, Court of Federal Claims No: 19–0393V
- Timothy Nabulsi, Lantana, Florida, Court of Federal Claims No: 19–0395V
- Dolores Walton, Boston, Massachusetts, Court of Federal Claims No: 19–0396V
- Jane B. Rushing, Mount Gilead, North Carolina, Court of Federal Claims No: 19–0397V
- Nadine Kraus, Buffalo, New York, Court of Federal Claims No: 19–0398V
- Katy Parrott, Austin, Texas, Court of Federal Claims No: 19–0401V
- John Gold on behalf of Norma A. Gold, Deceased, Elkhart, Indiana, Court of Federal Claims No: 19–0402V
- Jennifer Anderson, Minneapolis, Minnesota, Court of Federal Claims No: 19–0403V
- Christine Bedell on behalf of Thomas Bedell, Devereux, Florida, Court of Federal Claims No: 19–0404V
- Veronica Sanderson, Lakeville, Minnesota, Court of Federal Claims No: 19–0407V
- Jessica Davis on behalf of C.D., Philadelphia, Pennsylvania, Court of Federal Claims No: 19–0410V
- Marcus Smith, Brandywine, Maryland, Court of Federal Claims No: 19–0411V
- Tori Smith, Greenville, South Carolina, Court of Federal Claims No: 19–0412V
- Daniel Payne, Peoria, Arizona, Court of Federal Claims No: 19–0413V
- Johnny Matthews, Florence, South Carolina, Court of Federal Claims No: 19–0414V
- Tonya Lemay, Cranston, Rhode Island, Court of Federal Claims No: 19–0415V
- Gregory Bacon, Big Piney, Wyoming, Court of Federal Claims No: 19–0416V
- Andrea Keady, Wilmington, Delaware, Court of Federal Claims No: 19–0419V
- Dawn L. Bonsall, Medway, Maine, Court of Federal Claims No: 19–0420V
- Kenneth Gumm, Sr., Vero Beach, Florida, Court of Federal Claims No: 19–0421V
- Adam Gapen, Minneapolis, Minnesota, Court of Federal Claims No: 19–0422V
- Patricia Murray, Manalapan, New Jersey, Court of Federal Claims No: 19–0424V
- Carol Scott, Davidson, North Carolina, Court of Federal Claims No: 19–0427V
- Jeffrey Crosse, Aberdeen, Maryland, Court of Federal Claims No: 19–0429V
- Amy Thompson, Batavia, Illinois, Court of Federal Claims No: 19–0430V
- Odaine Tomlinson on behalf of Catelyn Rose Tomlinson, Manassas, Virginia, Court of Federal Claims No: 19–0431V
- John Mates, North Palm Beach, Florida, Court of Federal Claims No: 19–0432V

73. Katie M. Miller, Andover, Minnesota, Court of Federal Claims No: 19-0433V
74. Rebekah Fislser, Anderson, South Carolina, Court of Federal Claims No: 19-0434V
75. Christopher Lagos, Staten Island, New York, Court of Federal Claims No: 19-0436V
76. Maureen Nelson, Hempstead, New York, Court of Federal Claims No: 19-0438V
77. Jennifer Venier, Washington, District of Columbia, Court of Federal Claims No: 19-0439V
78. Sara Dorman, Paramus, New Jersey, Court of Federal Claims No: 19-0444V
79. Vera Veronica Kelly, Richmond, Virginia, Court of Federal Claims No: 19-0445V
80. Alexandra Friedman, Phoenix, Arizona, Court of Federal Claims No: 19-0446V
81. Susan Reifman, Boise, Idaho, Court of Federal Claims No: 19-0447V
82. Dameond Sigmond Reed, Charleston, South Carolina, Court of Federal Claims No: 19-0448V
83. Michelle A. Miller, Lancaster, New York, Court of Federal Claims No: 19-0450V
84. Cheri Sleeth, Boston, Massachusetts, Court of Federal Claims No: 19-0451V
85. Laurie L. Ogle, North Bend, Washington, Court of Federal Claims No: 19-0452V
86. Keyonna Michie on behalf of K.W., Bronx, New York, Court of Federal Claims No: 19-0453V
87. Robert Thomas Frey, Prospect, Kentucky, Court of Federal Claims No: 19-0454V
88. Darrell Barrett, Booneville, Kentucky, Court of Federal Claims No: 19-0456V
89. Roy Bristow, San Antonio, Texas, Court of Federal Claims No: 19-0457V
90. Cheryl Porter, Gainesville, Florida, Court of Federal Claims No: 19-0458V
91. Samantha Deters on behalf of S.D., Glen Burnie, Maryland, Court of Federal Claims No: 19-0459V
92. Ron Dimant and Christina Saczek on behalf of L.D., Boston, Massachusetts, Court of Federal Claims No: 19-0461V
93. Benjamin Larson, Washington, District of Columbia, Court of Federal Claims No: 19-0462V
94. Dwayne Palacio, Gardena, California, Court of Federal Claims No: 19-0466V
95. Amy Hatfield, Transfer, Pennsylvania, Court of Federal Claims No: 19-0467V
96. Lawrence Romine, Walnut Creek, California, Court of Federal Claims No: 19-0468V
97. Taylor Blackmore, Monterey, California, Court of Federal Claims No: 19-0470V

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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; Environmental Information Documentation, OMB No. 0915-0324—Revision****AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services.**ACTION:** Notice.

SUMMARY: In compliance with 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.

DATES: Comments on this ICR should be received no later than May 28, 2019.

ADDRESSES: Submit your comments, including the Information Collection Request 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: Environmental Information Documentation OMB No. 0915-0324—Revision.

Abstract: HRSA proposes revisions to the Environmental Information and Documentation (EID) checklist, which consists of information that the agency is required to obtain to comply with the

National Environmental Policy Act of 1969 (NEPA). NEPA establishes the federal government's national policy for protection of the environment. The EID checklist must be completed and submitted by applicants for HRSA funds that plan to engage in construction or other projects that would potentially impact the environment. HRSA utilizes the checklist to ensure that decision-making processes are consistent with NEPA. The revisions will update some of the language in the checklist. For example, to better align with 45 CFR part 75, HRSA proposes to change the term "grant" to "award" and "grantee" to "award recipient."

A 60-day notice was published in the **Federal Register** on December 27, 2018, Vol. 83, No. 247.

Need and Proposed Use of the Information: Applicants for HRSA funds must provide information and assurance of compliance with NEPA on the EID checklist. This information is reviewed in the pre-award stage.

Likely Respondents: HRSA applicants applying for federal construction grants and cooperative agreements.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
NEPA EID Checklist	1,500	1	1,500	1	1,500
Total	1,500		1,500		1,500