

product for which FDA has regulatory responsibility.

In the **Federal Register** of April 1, 2015 (80 FR 17439), FDA announced the availability of the draft guidance. Interested persons were invited to comment by June 1, 2015. FDA revised the guidance as appropriate in response to the comments. This guidance is intended to provide information for industry and for CDRH staff on the processes associated with a panel meeting held for any of the reasons identified in the guidance. This guidance replaces the "Guidance on Amended Procedures for Advisory Panel Meetings" (Ref. 2) and the guidance document entitled "Panel Review of Premarket Approval Applications #P91-2 blue book memo" (Ref. 3). This guidance supplements existing FDA Agency-wide guidance on the conduct of Advisory Committee meetings.

## 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 the panel meeting process for medical devices. 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>. Guidance documents are also available at <https://www.regulations.gov>. Persons unable to download an electronic copy of "Procedures for Meetings of the Medical Devices Advisory Committee" may send an email request to [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive an electronic copy of the document. Please use the document number 413 to identify the guidance you are requesting.

## IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. 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 21 CFR part 807, subpart E have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 860 have been approved under OMB control number 0910-0138; the collections of information in 21 CFR part 814 have been approved under OMB control number 0910-0231; and the collections of information in 21 CFR part 814, subpart H have been approved under OMB control number 0910-0332.

## V. References

The following references are on display in the Dockets Management Staff (see **ADDRESSES**), and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. CDRH's Medical Devices Advisory Committee, available at <https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/default.htm>.
2. "Guidance for Industry and FDA Staff: Guidance on Amended Procedures for Advisory Panel Meetings," July 2000, available at <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073726.pdf>.
3. "Panel Review of Premarket Approval Applications #P91-2 (blue book memo)," May 1991, available at <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081363.htm>.

Dated: August 28, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

[FR Doc. 2017-18549 Filed 8-31-17; 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, Acting 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 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 July 1, 2017, through July 31, 2017. 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: August 28, 2017.

**George Sigounas,**  
*Administrator.*

#### List of Petitions Filed

1. Houston Byrd, Jr., Heath, Ohio, Court of Federal Claims No: 17–0900V
2. Jacquelyn M. Will, Milwaukee, Wisconsin, Court of Federal Claims No: 17–0904V
3. Christine Midnight, Albuquerque, New Mexico, Court of Federal Claims No: 17–0905V
4. Beth Nemechek, Greeley, Colorado, Court of Federal Claims No: 17–0907V
5. Patricia Woolf, Cheyenne, Wyoming, Court of Federal Claims No: 17–0908V
6. Marie Schmidt, Naperville, Illinois, Court of Federal Claims No: 17–0913V
7. Richard K. Parker, Richmond, Virginia, Court of Federal Claims No: 17–0917V
8. Ronald Skrajner, Aurora, Ohio, Court of Federal Claims No: 17–0918V
9. Anita Javorski, Mankato, Minnesota, Court of Federal Claims No: 17–0919V
10. Jose Solis Marin, Washington, District of Columbia, Court of Federal Claims No: 17–0920V
11. Lavell Maize, Boston, Massachusetts, Court of Federal Claims No: 17–0921V
12. Ronald Patrick, Stuart, Florida, Court of Federal Claims No: 17–0922V
13. Amy Mehl, Memphis, Tennessee, Court of Federal Claims No: 17–0923V
14. Jennifer Stracick on behalf of H.S., St. Petersburg, Florida, Court of Federal Claims No: 17–0924V
15. Rebecca Curl, Winder, Georgia, Court of Federal Claims No: 17–0925V
16. Martin McGrail and Amy McGrail on behalf of S.M., Neptune, New Jersey, Court of Federal Claims No: 17–0926V
17. Elizabeth Evans, New York, New York, Court of Federal Claims No: 17–0929V
18. Arthur M. Flowers, III, West Columbia, South Carolina, Court of Federal Claims No: 17–0930V
19. Donna Ducey, Colleyville, Texas, Court of Federal Claims No: 17–0933V
20. Mary Orloski, Lewiston, Maine, Court of Federal Claims No: 17–0936V
21. Yvonne Simpson, Washington, District of Columbia, Court of Federal Claims No: 17–0944V
22. Leslie Questel on behalf of J.M., Big Bear, California, Court of Federal Claims No: 17–0946V
23. Erwin Casazza, Springfield, New Jersey, Court of Federal Claims No: 17–0947V
24. Tracie Johaneck, Washington, District of Columbia, Court of Federal Claims No: 17–0948V
25. Kimberly Holway, Seattle, Washington, Court of Federal Claims No: 17–0949V
26. Livanía Zavala, M.D. and Nelson J. Spinetti, M.D. on behalf of A.S., Edinburg, Texas, Court of Federal Claims No: 17–0951V
27. Fred A. Stover, Spring Mills, Pennsylvania, Court of Federal Claims No: 17–0952V
28. Justin M. Gillespie, Waupun, Wisconsin, Court of Federal Claims No: 17–0953V
29. Kevin McGuinness, Dade City, Florida, Court of Federal Claims No: 17–0954V
30. Kathleen Peddycord Wilson, Raleigh, North Carolina, Court of Federal Claims

No: 17–0955V

31. Jamie Gardner, Camp Hill, Pennsylvania, Court of Federal Claims No: 17–0959V
32. Sharifah Wilson, Philadelphia, Pennsylvania, Court of Federal Claims No: 17–0960V
33. William Brown, Vienna, Virginia, Court of Federal Claims No: 17–0961V
34. Karen Adams, Washington, District of Columbia, Court of Federal Claims No: 17–0963V
35. Stephen E. Antisdell, Buchanan, Michigan, Court of Federal Claims No: 17–0964V
36. Jennifer Gregorino, Chattanooga, Tennessee, Court of Federal Claims No: 17–0965V
37. Rowena Adcox, Bowling Green, Kentucky, Court of Federal Claims No: 17–0966V
38. Lisa Workman, Washington, District of Columbia, Court of Federal Claims No: 17–0967V
39. Mary Jane De La Pena, Sacramento, California, Court of Federal Claims No: 17–0971V
40. Mary Duncan, Washington, District of Columbia, Court of Federal Claims No: 17–0972V
41. Cindy Gilliam, Washington, District of Columbia, Court of Federal Claims No: 17–0974V
42. Jeffrey Braden, St. Louis, Missouri, Court of Federal Claims No: 17–0975V
43. Janice Condara, Sugar Land, Texas, Court of Federal Claims No: 17–0977V
44. George Kennedy, Austin, Texas, Court of Federal Claims No: 17–0978V
45. Daphne Lattimer, Groveport, Ohio, Court of Federal Claims No: 17–0980V
46. Linda Harris, Washington, District of Columbia, Court of Federal Claims No: 17–0981V
47. Kent Kemmerer, Willoughby, Ohio, Court of Federal Claims No: 17–0982V
48. Casey Humphreys on behalf of E.H., Jasper, Arkansas, Court of Federal Claims No: 17–0983V
49. Deborah Langer, Dallas, Texas, Court of Federal Claims No: 17–0984V
50. Allison Menard, Baton Rouge, Louisiana, Court of Federal Claims No: 17–0985V
51. William Nischbach, Washington, District of Columbia, Court of Federal Claims No: 17–0986V
52. Tzipora Lefkowitz on behalf of M.L., New Square, New York, Court of Federal Claims No: 17–0987V
53. Sara Torres-Ruiz, Palmdale, California, Court of Federal Claims No: 17–0988V
54. Jason Quirino, Boston, Massachusetts, Court of Federal Claims No: 17–0989V
55. Barbara Stoliker, Ventura, California, Court of Federal Claims No: 17–0990V
56. Natalie Ben-Shoshan, Dallas, Texas, Court of Federal Claims No: 17–0991V
57. Patricia Pendergrass, Washington, District of Columbia, Court of Federal Claims No: 17–0992V
58. Jamie Miller, Baltimore, Maryland, Court of Federal Claims No: 17–0993V
59. Regina Stenberg, Washington, District of Columbia, Court of Federal Claims No: 17–0994V
60. Cheri Lang, Washington, District of Columbia, Court of Federal Claims No:

- 17-0995V
61. Cheryl Conkle, Boston, Massachusetts, Court of Federal Claims No: 17-1001V
  62. Angela Dieter, Mount Joy, Pennsylvania, Court of Federal Claims No: 17-1002V
  63. Romana Estes, Boston, Massachusetts, Court of Federal Claims No: 17-1003V
  64. Anne Knudson, Phillips, Wisconsin, Court of Federal Claims No: 17-1004V
  65. Miguel Leal, Jr., Wyoming, Michigan, Court of Federal Claims No: 17-1008V
  66. Kimberly Settle, Thomasville, North Carolina, Court of Federal Claims No: 17-1009V
  67. Sapna Kadakia, Washington, District of Columbia, Court of Federal Claims No: 17-1011V
  68. Ricky Buras, Hattiesburg, Mississippi, Court of Federal Claims No: 17-1012V
  69. Ellisa Morine, Chicago, Illinois, Court of Federal Claims No: 17-1013V
  70. Margaret Rogers, Dresher, Pennsylvania, Court of Federal Claims No: 17-1014V
  71. Michael Anderson, Dresher, Pennsylvania, Court of Federal Claims No: 17-1017V
  72. Robert Wechsler, Dresher, Pennsylvania, Court of Federal Claims No: 17-1018V
  73. Geraldine Petrocelli, Monroe, New York, Court of Federal Claims No: 17-1019V
  74. Kevin McKenna, Rochester Hills, Michigan, Court of Federal Claims No: 17-1021V
  75. Albert Parsons, Wartburg, Tennessee, Court of Federal Claims No: 17-1022V
  76. Cynthia Hackney, San Antonio, Texas, Court of Federal Claims No: 17-1027V
  77. Barbara Sakovits, Dresher, Pennsylvania, Court of Federal Claims No: 17-1028V
  78. Sheryl Attig, Greenville, South Carolina, Court of Federal Claims No: 17-1029V
  79. Patricia Anton, Dresher, Pennsylvania, Court of Federal Claims No: 17-1031V
  80. Tasha Lee and Jose Botello on behalf of A.B., Beverly Hills, California, Court of Federal Claims No: 17-1032V

[FR Doc. 2017-18567 Filed 8-31-17; 8:45 am]

**BILLING CODE 4165-15-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center For Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which

would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR 14-166: Early Phase Clinical Trials in Imaging and Image-Guided Interventions.

*Date:* September 25, 2017.

*Time:* 4:00 p.m. to 7:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

*Contact Person:* Songtao Liu, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5108, Bethesda, MD 20817, 301-435-3578, [songtao.liu@nih.gov](mailto:songtao.liu@nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

*Dated:* August 29, 2017.

**Natasha M. Copeland,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2017-18612 Filed 8-31-17; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; R13 Conference Grant Applications.

*Date:* September 21, 2017.

*Time:* 11:00 a.m. to 12:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Jian Yang, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7111, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-7799, [yangj@extra.niddk.nih.gov](mailto:yangj@extra.niddk.nih.gov).

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Time-Sensitive Obesity PAR Review.

*Date:* September 29, 2017.

*Time:* 1:30 p.m. to 3:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Michele L. Barnard, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7353, 6707 Democracy Boulevard, Bethesda, MD 20892-2542, (301) 594-8898, [barnardm@extra.niddk.nih.gov](mailto:barnardm@extra.niddk.nih.gov).

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; DDK-D Member Conflict SEP.

*Date:* October 6, 2017.

*Time:* 8:00 a.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Xiaodu Guo, MD, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7023, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-4719, [guox@extra.niddk.nih.gov](mailto:guox@extra.niddk.nih.gov).

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Fellowships in Digestive Diseases and Nutrition.

*Date:* October 12-13, 2017.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

*Contact Person:* Jian Yang, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7111, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-7799, [yangj@extra.niddk.nih.gov](mailto:yangj@extra.niddk.nih.gov).

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Fellowships in Diabetes, Endocrinology and Metabolic Diseases.

*Date:* October 17, 2017.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Doubletree Hotel Bethesda (Formerly Holiday Inn Select), 8120 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Thomas A. Tatham, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7021, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-3993, [tatham@mail.nih.gov](mailto:tatham@mail.nih.gov).