by one of the following methods: Wire transfer, electronically, check, bank draft, or U.S. postal money order made payable to the Food and Drug Administration. The preferred payment method is online using an electronic check (Automated Clearing House (ACH), also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). Secure electronic payments can be submitted using the User Fees Payment Portal at https://userfees.fda.gov/pay or the Pay.gov. payment option is available to you after you submit a cover sheet. (Note: only full payments are accepted. No partial payments can be made online.) Once you have found your invoice, select “Pay Now” to be redirected to Pay.gov. Electronic payment options are based on the balance due. Payment by credit card is available only for balances less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

When paying by check, bank draft, or U.S. postal money order, please write your application’s unique Payment Identification Number, beginning with the letters “AG”, on the upper right-hand corner of your completed Animal Generic Drug User Fee Cover Sheet. Also write the FDA post office box number (P.O. Box 979033) on the enclosed check, bank draft, or money order. Mail the payment and a copy of the completed Animal Generic Drug User Fee Cover Sheet to: Food and Drug Administration, P.O. Box 979033, St. Louis, MO 63197–9000.

When paying by wire transfer, it is required that the invoice number is included; without the invoice number the payment may not be applied. If the payment amount is not applied, the invoice amount would be referred to collections. The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee, it is required to add that amount to the payment to ensure that the invoice is paid in full. Use the following account information when sending a wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Account Name: Food and Drug Administration, Account No.: 75060099, Routing No.: 021030004, Swift No.: FRNYUS33.

To send a check by a courier such as Federal Express, the courier must deliver the check and printed copy of the cover sheet to: U.S. Bank, Attn: Government Lockbox 979033, 1005 Government Lockbox 979033, St. Louis, MO 63101. (Note: This address is for courier delivery only. If you have any questions concerning courier delivery, contact U.S. Bank at 314–418–4013. This phone number is only for questions about courier delivery.)

It is important that the fee arrives at the bank at least a day or two before the abbreviated application arrives at FDA’s CVM. FDA records the official abbreviated application receipt date as the later of the following: The date the application was received by CVM, or the date U.S. Bank notifies FDA that your payment in the full amount has been received, or when the U.S. Department of the Treasury notifies FDA of payment. U.S. Bank and the United States Treasury are required to notify FDA within 1 working day, using the Payment Identification Number described previously.

The tax identification number of FDA is 53–0196965. (Note: In no case should the payment for the fee be submitted to FDA with the application.)

B. Application Cover Sheet Procedures

Step One—Create a user account and password. Log onto the AGDUFA website at https://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/ucm137049.htm and scroll down the page until you find the link “Create AGDUFA User Fee Cover Sheet.” Select that link and follow the directions. For security reasons, each firm submitting an application will be assigned an organization identification number, and each user will also be required to set up a user account and password the first time you use this site. Online instructions will walk you through this process.

Step Two—Create an Animal Generic Drug User Fee Cover Sheet, transmit it to FDA, and print a copy. After logging into your account with your user name and password, complete the steps required to create an Animal Generic Drug User Fee Cover Sheet. One cover sheet is needed for each abbreviated animal drug application. Once you are satisfied that the data on the cover sheet is accurate and you have finalized the cover sheet, you will be able to transmit it electronically to FDA and you will be able to print a copy of your cover sheet showing your unique Payment Identification Number.

Step Three—Send the payment for your application as described in section VIII.A.

Step Four—Please submit your application and a copy of the completed Animal Generic Drug User Fee Cover Sheet to the following address: Food and Drug Administration, Center for Veterinary Medicine, Document Control Unit (HFV–199), 7500 Standish Pl., Rockville, MD 20855.

C. Product and Sponsor Fees

By December 31, 2018, FDA will issue invoices and payment instructions for product and sponsor fees for FY 2019 using this fee schedule. Fees will be due by January 31, 2019. FDA will issue invoices in November 2019 for any products and sponsors subject to fees for FY 2019 that qualify for fees after the December 2018 billing.

Leslie Kux, Associate Commissioner for Policy.
[FR Doc. 2018–20912 Filed 9–25–18; 8:45 am]
BILLING CODE 4164–01–P
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 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 “within 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 August 1, 2018, through August 31, 2018. 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, HealthCareSystems 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.


George Sigounas, Administrator.

List of Petitions Filed

1. Dustin Bradley, San Diego, California, Court of Federal Claims No: 18–1123V
2. Richard Bishop, La Crosse, Wisconsin, Court of Federal Claims No: 18–1126V
3. Jocelyn Banda on behalf of A. B., El Centro, California, Court of Federal Claims No: 18–1127V
4. Dorothy J. Kapp, Louisville, Kentucky, Court of Federal Claims No: 18–1128V
5. Angela Beasley, Birmingham, Alabama, Court of Federal Claims No: 18–1130V
6. Terry Thornton, Huntsville, Alabama, Court of Federal Claims No: 18–1131V
7. Violet J. Barino, Florence, South Carolina, Court of Federal Claims No: 18–1132V
9. Yarah Alicea and Nicholas Kontos on behalf of V. K., Cutler Bay, Florida, Court of Federal Claims No: 18–1136V
10. Rabia Malik, Franklin, Ohio, Court of Federal Claims No: 18–1138V
11. Iris J. Jackson, Snellville, Georgia, Court of Federal Claims No: 18–1143V
12. Kathryn Nelson, Stillwater, Minnesota, Court of Federal Claims No: 18–1144V
14. Stacie Wilson, Hiawatha, Kansas, Court of Federal Claims No: 18–1148V
15. Gretchen Handy, Grand Forks, North Dakota, Court of Federal Claims No: 18–1149V
17. Robert Jamison, Harrison, Michigan, Court of Federal Claims No: 18–1152V
18. Evelyn Mazmanian, Cambridge, Massachusetts, Court of Federal Claims No: 18–1153V
19. Derek Roberts on behalf of Willie Roberts, Jr., Deceased, Seattle, Washington, Court of Federal Claims No: 18–1156V
20. Yovanny Alonzo, Bronx, New York, Court of Federal Claims No: 18–1157V
22. Beverly Ford, Temple, Texas, Court of Federal Claims No: 18–1160V
23. Heather Doucette, Ocala, Florida, Court of Federal Claims No: 18–1161V
25. Wayne F. Grant, Lakeland, Florida, Court of Federal Claims No: 18–1163V
26. Bonni Jean Arnold, Poway, California, Court of Federal Claims No: 18–1164V
27. Ashley Barkocy on behalf of M. B., Destin, Florida, Court of Federal Claims No: 18–1175V
29. Rosa M. Rios Morales and Juan Enrique Lozada Virella on behalf of I. K. L. R., Barranquitas, Puerto Rico, Court of Federal Claims No: 18–1190V
31. Kathryn E. McCreary, Amherst, New York, Court of Federal Claims No: 18–1194V
32. Tara Brooks, Prescott Valley, Arizona, Court of Federal Claims No: 18–1195V
33. Patrick L. Magliozi, Carmel, Indiana, Court of Federal Claims No: 18–1196V
34. Susan Mogavero, San Diego, California, Court of Federal Claims No: 18–1197V
35. Robert Wharton and Debra Wharton on behalf of B.W., Boston, Massachusetts, Court of Federal Claims No: 18–1198V
36. Lucy Moore, Clifton, New York, Court of Federal Claims No: 18–1199V
37. Abeje Schnake, Glendale, Wisconsin, Court of Federal Claims No: 18–1201V
38. Shannon Delehanty, Conover, North Carolina, Court of Federal Claims No: 18–1202V
39. Christina Mecklenburg on behalf of H.M., Laguna Niguel, California, Court of Federal Claims No: 18–1203V
40. Megan McDonald on behalf of Malayna Grace McDonald, Patchogue, New York, Court of Federal Claims No: 18–1204V
41. Palestine McGowen, Tyler, Texas, Court of Federal Claims No: 18–1205V
42. Franline Lucinda Destin, North Miami, Florida, Court of Federal Claims No: 18–1206V
43. Lindsey Hettish, Coraopolis, Pennsylvania, Court of Federal Claims No: 18–1207V
44. Nancy Rissler, Frisco, Texas, Court of Federal Claims No: 18–1208V
45. Christina Christopher, White Oak, Pennsylvania, Court of Federal Claims No: 18–1209V
46. Garrett D. Polowy, Fairfax, Virginia, Court of Federal Claims No: 18–1210V
47. Dalvinder Singh Bains and Gurpal Kaur Bains on behalf of K.S.B., Yuba City, California, Court of Federal Claims No: 18–1211V
48. Leonard Thompson, Midland, Michigan, Court of Federal Claims No: 18–1212V
49. Barbara King Van Osdol, Indianapolis, Indiana, Court of Federal Claims No: 18–1213V
50. Thomas Schuster, Rogers, Minnesota, Court of Federal Claims No: 18–1214V
51. William O. Ledbetter, Piedmont, Alabama, Court of Federal Claims No: 18–1215V
52. Jean Golden, Clayton, New York, Court of Federal Claims No: 18–1216V
53. Mary McNally, Dresher, Pennsylvania, Court of Federal Claims No: 18–1217V
55. Dale Kilpatrick, Seattle, Washington, Court of Federal Claims No: 18–1219V
56. Leslie Nan Moon, North Bend, Washington, Court of Federal Claims No: 18–1220V
57. Ryan Hodges on behalf of S.H., Knotts Island, North Carolina, Court of Federal Claims No: 18–1221V
58. Kurt Sonnenburg, Madison, Wisconsin, Court of Federal Claims No: 18–1222V
60. Jean Stone, Riverdale, New Jersey, Court of Federal Claims No: 18–1224V
61. Laurie Barreiro, Greensboro, North Carolina, Court of Federal Claims No: 18–1225V
62. Teresa Ortiz, Stockton, California, Court of Federal Claims No: 18–1226V
63. Elizabeth Salazar on behalf of D.R., Houston, Texas, Court of Federal Claims No: 18–1227V
64. Basil McNeely, Mobile, Alabama, Court of Federal Claims No: 18–1228V
66. Kayla Neuenschwander, Liberty Hill, Texas, Court of Federal Claims No: 18–1230V
67. Stephanie Scott, Washington, District of Columbia, Court of Federal Claims No: 18–1231V
68. Robert J. Lang, Palmdale, California, Court of Federal Claims No: 18–1232V
69. Cynthia L. Kiegel, Newburgh, Indiana, Court of Federal Claims No: 18–1233V
70. Carey Shimada, Layton, Utah, Court of Federal Claims No: 18–1234V
71. Brooke Cloyd and Dylan Cloyd on behalf of B.T.C., Dallas, Texas, Court of Federal Claims No: 18–1235V
73. Norma Keller on behalf of Elizabeth Keller, Greensboro, North Carolina, Court of Federal Claims No: 18–1237V
74. Ashley Muller, Phoenix, Arizona, Court of Federal Claims No: 18–1238V
75. Tennie Komar, Boston, Massachusetts, Court of Federal Claims No: 18–1239V
76. Gerard Pepeta, Boston, Massachusetts, Court of Federal Claims No: 18–1240V
77. Donna Stearns, Washington, District of Columbia, Court of Federal Claims No: 18–1241V
79. Tina Furlano, Pittsburgh, Pennsylvania, Court of Federal Claims No: 18–1243V
80. Ryan Bronson, Tampa, Florida, Court of Federal Claims No: 18–1244V
81. Lori A. Hildebrand, Pittsburgh, Pennsylvania, Court of Federal Claims No: 18–1245V
82. Richard Westfall, Burlington, North Carolina, Court of Federal Claims No: 18–1246V
83. Gloria Kirkpatrick, Cleveland, Tennessee, Court of Federal Claims No: 18–1247V
84. Sherrie Sandoval on behalf of Robert Sandoval, Deceased, Los Alamos, New Mexico, Court of Federal Claims No: 18–1248V
85. Latoria Martin, King of Prussia, Pennsylvania, Court of Federal Claims No: 18–1249V
86. Dianah Hernandez, Mineola, New York, Court of Federal Claims No: 18–1250V
87. Brian Gribbon, Peoria, Arizona, Court of Federal Claims No: 18–1251V
88. Shabnam Kouchak, Detroit, Michigan, Court of Federal Claims No: 18–1252V
89. Monica Hill, Dickinson, North Dakota, Court of Federal Claims No: 18–1253V
90. Melissa Papineau, Wichita, Kansas, Court of Federal Claims No: 18–1254V
91. Dolores A. Gorczyca, Memphis, Tennessee, Court of Federal Claims No: 18–1255V
93. Cynthia Pryor and Freddie Pryor, Jr. on behalf of L.P., Phoenix, Arizona, Court of Federal Claims No: 18–1257V
95. Terri L. Vanderjack, Westmont, Illinois, Court of Federal Claims No: 18–1259V
96. Donald Wolls, Blue Ash, Ohio, Court of Federal Claims No: 18–1260V
97. Lisa Olexa, Skillman, New Jersey, Court of Federal Claims No: 18–1261V
98. Craig Johnson, Bayport, Minnesota, Court of Federal Claims No: 18–1262V
100. Franklin Gallo, Washington, District of Columbia, Court of Federal Claims No: 18–1264V
DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; 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: National Institute on Aging Special Emphasis Panel; Next Generation Clinical Researchers in AD/ADRD.

Date: October 29, 2018.
Time: 8:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Bethesda Marriott Hotel, 5151 Pooks Hill Rd., Bethesda, MD 20814.
Contact Person: Isis S. Mikhail, MD, MPH, DRPH, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301–402–7704, MIKHAIL@MAIL.NIH.GOV.

(Catalogue of Federal Domestic Assistance Program Nos. 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Melanie J. Pantoja,
Program Analyst, Office of Federal Advisory Committee Policy.

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