drug applications (ANDAs) for tromethamine injectable, 3.6g/100 mL, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Katelyn Mineo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6213, Silver Spring, MD 20993–0002, 301–796–1054.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

THAM Solution (tromethamine) injectable, 3.6 g/100 mL, is the subject of NDA 013025, held by Hospira, Inc., and initially approved on December 16, 1965. THAM Solution is indicated for the prevention and correction of metabolic acidosis.

In a letter dated February 26, 2018, Pfizer Inc., Hospira, Inc.'s parent company, notified FDA that THAM Solution (tromethamine) injectable, 3.6 g/100 mL, was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Arent Fox LLP submitted a citizen petition dated January 30, 2019 (Docket No. FDA–2019–P–0692), under 21 CFR 10.30, requesting that the Agency determine whether THAM Solution (tromethamine) injectable, 3.6 g/100 mL, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that THAM Solution (tromethamine) injectable, 3.6 g/100 mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that THAM Solution (tromethamine) injectable, 3.6 g/100 mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of THAM Solution (tromethamine) injectable, 3.6 g/100 mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list THAM Solution (tromethamine) injectable, 3.6 g/100 mL, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to THAM Solution (tromethamine) injectable, 3.6 g/100 mL, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: June 27, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–14146 Filed 7–2–19; 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 (the Court) 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 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 May 1, 2019, through May 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 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: June 27, 2019.

George Sigounas,

Administrator.

List of Petitions Filed

1. Shane Bowers, Waupun, Wisconsin, Court of Federal Claims No: 19–0644V
2. Lynn Acton, New Haven, Connecticut, Court of Federal Claims No: 19–0647V
3. Michele Louise Gray, Lancaster, California, Court of Federal Claims No: 19–0648V
4. Shelley Haynes on behalf of E. H., Mountain City, Tennessee, Court of Federal Claims No: 19–0651V
5. John Hardy Bauer, Twin Falls, Idaho, Court of Federal Claims No: 19–0652V
6. Delinda Smith, Stuttgart, Arkansas, Court of Federal Claims No: 19–0653V
7. Harold Kaplan, Marlton, New Jersey, Court of Federal Claims No: 19–0654V
8. Gladys Wright, Minneapolis, Minnesota, Court of Federal Claims No: 19–0659V
9. Shannon McTernan, Columbia, Missouri, Court of Federal Claims No: 19–0662V
10. Larry Logan, Mustang, Oklahoma, Court of Federal Claims No: 19–0666V
11. Geoff Mead on behalf of M. M., Nanuet, New York, Court of Federal Claims No: 19–0667V
12. Ingrid Minge, Columbia, Missouri, Court of Federal Claims No: 19–0668V
13. Tara Blaise, Huntington Station, New York, Court of Federal Claims No: 19–0670V
14. Rebekah R. Linnett, Astoria, Oregon, Court of Federal Claims No: 19–0672V
15. Gina Binkley Kotch, New York, New York, Court of Federal Claims No: 19–0675V
16. Gary Marco, Bedford, Ohio, Court of Federal Claims No: 19–0677V
17. Branch R. Lew, Fort Wayne, Indiana, Court of Federal Claims No: 19–0679V
18. Felix Willis, Waupun, Wisconsin, Court of Federal Claims No: 19–0680V
19. Rheanan Hoffman, Milwaukee, Wisconsin, Court of Federal Claims No: 19–0681V
20. Lucinda Laird, Salem, Oregon, Court of Federal Claims No: 19–0682V
21. Keith Franco, Smyrna, Georgia, Court of Federal Claims No: 19–0684V
22. Judith Markey, Boston, Massachusetts, Court of Federal Claims No: 19–0687V
23. Kelly Stevens, Clackamas, Oregon, Court of Federal Claims No: 19–0689V
24. Nicholas Catone and Marjorie Catone on behalf of N. C., Deceased, Brick, New Jersey, Court of Federal Claims No: 19–0690V
25. Carolyn Clark, Newark, Ohio, Court of Federal Claims No: 19–0692V
26. Winnifer Kinsey, Slidell, Louisiana, Court of Federal Claims No: 19–0695V
27. Jennifer Dorso, San Antonio, Texas, Court of Federal Claims No: 19–0699V
28. Ernest Ghent, Reno, Nevada, Court of Federal Claims No: 19–0700V
29. Antonio Perez, San Antonio, Texas, Court of Federal Claims No: 19–0702V
30. Laurie Tennessen, Monticello, Minnesota, Court of Federal Claims No: 19–0703V
31. Michael Lucero, Santa Fe, New Mexico, Court of Federal Claims No: 19–0704V
32. Patrick W. Wilson, San Rafael, California, Court of Federal Claims No: 19–0705V
33. L Ruther, Deceased, Orlando, Florida, Court of Federal Claims No: 19–0706V
34. Steven S. Floyd, Memphis, Tennessee, Court of Federal Claims No: 19–0707V
35. William Jenne, Greenlawn, New York, Court of Federal Claims No: 19–0708V
36. John Barry Thomas, Telford, Pennsylvania, Court of Federal Claims No: 19–0709V
37. Christopher Cartwright, Denville, New Jersey, Court of Federal Claims No: 19–0712V
38. Helen Leonard, Ypsilanti, Michigan, Court of Federal Claims No: 19–0714V
39. Anne M. Schubert on behalf of R. S., Elk Grove, California, Court of Federal Claims No: 19–0715V
40. Colleen M. McNerney, Rochester, New York, Court of Federal Claims No: 19–0717V
41. Sherri Cheek, Louisville, Kentucky, Court of Federal Claims No: 19–0718V
42. Geri Meyer, Clarksville, Arkansas, Court of Federal Claims No: 19–0719V
43. Carole Debreczenyi, Maywood, Illinois, Court of Federal Claims No: 19–0721V
44. Victoria Gauvin, Burlington, Vermont, Court of Federal Claims No: 19–0722V
45. Sherly Smith on behalf of Chauncey Smith, Jr., Miami Gardens, Florida, Court of Federal Claims No: 19–0723V
46. Sanders Robinson, Montgomery, Alabama, Court of Federal Claims No: 19–0725V
47. Frank Gibbs, Washington, District of Columbia, Court of Federal Claims No: 19–0726V
48. Fabray Turner, Boston, Massachusetts, Court of Federal Claims No: 19–0727V
49. Ricardo Rodriguez, Farmers Branch, Texas, Court of Federal Claims No: 19–0729V
50. Tammy Robinson, Boston, Massachusetts, Court of Federal Claims No: 19–0730V
51. Michelle Gonzales, Tehachapi, California, Court of Federal Claims No: 19–0731V
52. Christopher Crowley, Dorchester, Massachusetts, Court of Federal Claims No: 19–0732V
53. Michael Wilkinson, Edina, Minnesota, Court of Federal Claims No: 19–0733V
54. Kathryn Larson, Boston, Massachusetts, Court of Federal Claims No: 19–0734V
55. Liang Zhao on behalf of G. L., Davenport, Iowa, Court of Federal Claims No: 19–0735V
56. James Remmes, Charlestown, Massachusetts, Court of Federal Claims No: 19–0736V
57. Edward Carroll, New York, New York,

Court of Federal Claims No: 19–0737V
58. Sheila Amati, Monongahela, Pennsylvania, Court of Federal Claims No: 19–0738V
59. Michael Moses on behalf of P. M., Milwaukee, Wisconsin, Court of Federal Claims No: 19–0739V
60. Tina Coppersmith, Glen Falls, New York, Court of Federal Claims No: 19–0741V
61. Kelsey Metsker, Shawnee Mission, Kansas, Court of Federal Claims No: 19–0743V
62. Patricia Taylor on behalf of A. S., San Antonio, Texas, Court of Federal Claims No: 19–0744V
63. Renee Smith, Luling, Louisiana, Court of Federal Claims No: 19–0745V
64. Virginia Van Zandt, San Francisco, California, Court of Federal Claims No: 19–0746V
65. John Heath and Marie Louise Heath on behalf of J. N. H., San Mateo, California, Court of Federal Claims No: 19–0749V
66. Linda Goggins, Pottstown, Pennsylvania, Court of Federal Claims No: 19–0751V
67. Sally Stokes, Washington, District of Columbia, Court of Federal Claims No: 19–0752V
68. Lance Basting, Eau Claire, Wisconsin, Court of Federal Claims No: 19–0753V
69. Wendy Jacobs, Mankato, Minnesota, Court of Federal Claims No: 19–0761V
70. Mark Santia, Erie, Pennsylvania, Court of Federal Claims No: 19–0762V
71. Young Kwan Jun, Brodheadsville, Pennsylvania, Court of Federal Claims No: 19–0764V
72. John F. Olson, Mankato, Minnesota, Court of Federal Claims No: 19–0768V
73. Yaniris Gonzalez, Brooklyn, New York, Court of Federal Claims No: 19–0769V
74. Chelsea Delvecchio, Tucson, Arizona, Court of Federal Claims No: 19–0772V
75. Beth Wyatt, Sedro-Woolley, Washington, Court of Federal Claims No: 19–0773V
76. Shawn Steiger, Boise, Idaho, Court of Federal Claims No: 19–0775V
77. Kathi Leopard, Greenwood, South Carolina, Court of Federal Claims No: 19–0776V
78. Ines Chicos on behalf of L.C., Sunnyside, New York, Court of Federal Claims No: 19–0778V
79. Linda Bergstrom, Park Ridge, Illinois, Court of Federal Claims No: 19–0784V
80. Natalie A. Woodson, Staten Island, New York, Court of Federal Claims No: 19–0785V
81. Charley Boon, El Cajon, California, Court of Federal Claims No: 19–0788V
82. Arthur Cordisco, Boston, Massachusetts, Court of Federal Claims No: 19–0789V
83. Carol Culwell, Bryan, Texas, Court of Federal Claims No: 19–0790V
84. James G. Strouse, Greensboro, North Carolina, Court of Federal Claims No: 19–0793V
85. Stephanie Hetrick and Jonathan Hetrick on behalf of J H, Ruston, Louisiana, Court of Federal Claims No: 19–0795V
86. Cynthia Paul, Sarasota, Florida, Court of Federal Claims No: 19–0797V
87. Jeffrey Scott Cantrell, Greensboro, North Carolina, Court of Federal Claims No: 19–0799V
88. Kimble Lehman, Paducah, Kentucky, Court of Federal Claims No: 19–0802V
89. Jeremy Williams, Washington, District of Columbia, Court of Federal Claims No: 19–0803V
90. Michael Thomas, Washington, District of Columbia, Court of Federal Claims No: 19–0804V
91. Keith Ratay, Washington, District of Columbia, Court of Federal Claims No: 19–0805V
92. Scott Weaver, Washington, District of Columbia, Court of Federal Claims No: 19–0806V

[FR Doc. 2019–14124 Filed 7–2–19; 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 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: Center for Scientific Review Special Emphasis Panel; Member Conflict: International and Cooperative Projects 1.

Date: July 26, 2019.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health; 6701 Rockledge Drive Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Brian H. Scott, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive Bethesda, MD 20892, 301–827–7490, *brianscott@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Planning for Non-Communicable Diseases and Disorders Research Training Programs.

Date: July 26, 2019.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Brian H Scott, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review 6701 Rockledge Drive, Bethesda, MD 20892, 301–827–7490, *brianscott@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Molecular Virology, Cell Biology and Drug Development.

Date: July 30–31, 2019.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: John C Pugh, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1206, MSC 7808, Bethesda, MD 20892, (301) 435–2398, *pughjohn@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: AIDS and Related Research.

Date: July 30, 2019.

Time: 10:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Barna Dey, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3184 Bethesda, MD 20892, 301–451–2796 *bdey@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR–18–022/023: Tobacco Use and HIV in Low and Middle Income Countries.

Date: July 30, 2019.

Time: 11:30 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Mark P Rubert, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5218, MSC 7852 Bethesda, MD 20892, 301–435–1775 *rubertm@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR 18–877: Early Stage Clinical Trials for the Spectrum of Alzheimer's Disease and Age-related Cognitive Deficits

Date: July 30–31, 2019.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Unja Hayes, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive Bethesda, MD 20892, 301–827–6830 *unja.hayes@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Neurodegeneration.

Date: July 30, 2019.

Time: 12:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.