phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product KYNAMRO (mipomersen sodium). KYNAMRO is indicated as an adjunct to lipid-lowering medications and diet to reduce low density lipoprotein-cholesterol, apolipoprotein B, total cholesterol, and non-high density lipoprotein-cholesterol in patients with homozygous familial hypercholesterolemia. Subsequent to this approval, the USPTO received a patent term restoration application for KYNAMRO (U.S. Patent No. 7,511,131) from Genzyme Corporation, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 27, 2014, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of KYNAMRO represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for KYNAMRO is 2,601 days. Of this time, 2,294 days occurred during the testing phase of the regulatory review period, while 307 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* December 18, 2005. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on December 18, 2005.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* March 29, 2012. FDA has verified the applicant's claim that the new drug application (NDA) for KYNAMRO (NDA 203568) was submitted on March 29, 2012.

3. *The date the application was approved:* January 29, 2013. FDA has verified the applicant's claim that NDA 203568 was approved on January 29, 2013.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 853 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by June 23, 2015. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by October 21, 2015. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written or electronic petitions. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to *http://www.regulations.gov,* Docket No. FDA–2013–S–0610.

Comments and petitions that have not been made publicly available on *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 20, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–09522 Filed 4–23–15; 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, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (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 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 the 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 11C–26, Rockville, MD 20857; (301) 443–6593.

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 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 Section 2114 of the PHS Act or as set forth at 42 CFR 100.3, as applicable. 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, 2015, through March 31, 2015. 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. ''Sustained, 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. ''Sustained, 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, Room 11C–26, 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.

Dated: April 17, 2015.

James Macrae,

Acting Administrator.

List of Petitions Filed

1. Leanna Babb, Yuma, Arizona, Court of Federal Claims No: 15–0195V
2. Avery Kranz and Alyssa Kranz on behalf of M. K., Millburn, New Jersey, Court of Federal Claims No: 15–0196V
3. Avery Kranz, Millburn, New Jersey, Court of Federal Claims No: 15–0197V
4. Carol Williams, Morgantown, West Virginia, Court of Federal Claims No: 15–0198V
5. Thomas Holland, Cataumet, Massachusetts, Court of Federal Claims No: 15–0199V
6. Mario Caruso, Clovis, California, Court of Federal Claims No: 15–0200V
7. Marilyn Akyuz, Brooklyn, New York, Court of Federal Claims No: 15–0201V
8. Andrew Bussa, Boston, Massachusetts, Court of Federal Claims No: 15–0202V
9. Peggy Lafon, Crowley, Texas, Court of Federal Claims No: 15–0203V
10. Rosemary St. George, Boston, Massachusetts, Court of Federal Claims No: 15–0204V
11. David G. Smith, Billerica, Massachusetts, Court of Federal Claims No: 15–0205V
12. Carin Ing-Marie Malkin, Sarasota, Florida, Court of Federal Claims No: 15–0206V
13. Tamie Blesi, Minneapolis, Minnesota, Court of Federal Claims No: 15–0208V
14. Tamie Blesi, Minneapolis, Minnesota, Court of Federal Claims No: 15–0209V
15. James Collins, Jr., Concord, North Carolina, Court of Federal Claims No: 15–0210V
16. Annabella Chin, Pembroke, Florida, Court of Federal Claims No: 15–0214V
17. Tisia Green, Cheektowaga, New York, Court of Federal Claims No: 15–0218V
18. Tate Takahashi, Honolulu, Hawaii, Court of Federal Claims No: 15–0219V
19. Dorothy Keegan, Rochester, New York, Court of Federal Claims No: 15–0220V
20. Brandene LaPorte, Philadelphia, Pennsylvania, Court of Federal Claims No: 15–0221V
21. Melvin Keith Castle, New Bern, North Carolina, Court of Federal Claims No: 15–0222V
22. Sarah Yoon on behalf of N.Y., Valencia, California, Court of Federal Claims No: 15–0224V
23. Bernard Halverson on behalf of Susan Halverson, Deceased, Somers Point, New Jersey, Court of Federal Claims No: 15–0227V
24. Jean L. Buck, Las Vegas, Nevada, Court of Federal Claims No: 15–0231V
25. Joseph Bourche, Boulder, Colorado, Court of Federal Claims No: 15–0232V
26. Keith Saunders, Onawa, Iowa, Court of Federal Claims No: 15–0233V
27. Mary Axelson on behalf of A. A., Phoenix, Arizona, Court of Federal Claims No: 15–0234V
28. Kristen Silverio on behalf of G. L., Phoenix, Arizona, Court of Federal Claims No: 15–0235V
29. Phyllis Phipps, Bluffton, Indiana, Court of Federal Claims No: 15–0238V
30. Travis Morgan, Franklin, Tennessee, Court of Federal Claims No: 15–0239V
31. Carl S. Fish, Folsom, California, Court of Federal Claims No: 15–0244V
32. Rami Hatter, Dale City, California, Court of Federal Claims No: 15–0245V
33. Tarah Gramza on behalf of J. G., Mesa, Arizona, Court of Federal Claims No: 15–0247V
34. Angela Bogue, Louisburg, North Carolina, Court of Federal Claims No: 15–0250V
35. Joseph Willett, Wake Forest, North Carolina, Court of Federal Claims No: 15–0252V
36. Scott Siciliano and Kathleen Siciliano on behalf of E. S., Smithtown, New York, Court of Federal Claims No: 15–0253V
37. Janet Florence, Glassboro, New Jersey, Court of Federal Claims No: 15–0255V
38. Allison Boman on behalf of R. B., Rock Springs, Wyoming, Court of Federal Claims No: 15–0256V
39. Jordan Holtz, Sussex, Wisconsin, Court of Federal Claims No: 15–0257V
40. Robert Richie, Atoka, Oklahoma, Court of Federal Claims No: 15–0258V
41. Sandra E. Horvath, San Jose, California, Court of Federal Claims No: 15–0260V
42. Lawrence Marra, Jr., Bethlehem, Pennsylvania, Court of Federal Claims No: 15–0261V
43. Ameena Jaafar on behalf of A. M., Windsor, Connecticut, Court of Federal Claims No: 15–0267V
44. Brian Badger, Owensboro, Kentucky, Court of Federal Claims No: 15–0273V
45. John Harbrucker, Kansas City, Kansas, Court of Federal Claims No: 15–0274V
46. Maureen McGrath, Sturgeon Bay, Wisconsin, Court of Federal Claims No: 15–0275V
47. Jane Privitera, Baldwin, New York, Court of Federal Claims No: 15–0276V
48. Raquel Davis on behalf of M. D., Boston, Massachusetts, Court of Federal Claims No: 15–0277V
49. Janice Schroeder, Austin, Texas, Court of Federal Claims No: 15–0278V
50. Brittany Stallings Benoit and Arsene Benoit on behalf of Gabriel Cash Benoit, Deceased, Quitman, Mississippi, Court of Federal Claims No: 15–0279V
51. Annette Dominguez and Lydia Fazekas on behalf of Rebecca C. Arana, Deceased, Beverly Hills, California, Court of Federal Claims No: 15–0280V
52. Rita Glynn, St. Paul, Minnesota, Court of Federal Claims No: 15–0283V
53. Malissa Ajeti, Gilroy, California, Court of Federal Claims No: 15–0284V
54. Shawn Orgel-Olson, Boston, Massachusetts, Court of Federal Claims No: 15–0285V
55. George Swaiss, Santa Clara, California, Court of Federal Claims No: 15–0286V
56. Ann Wyborski, Vienna, Virginia, Court of Federal Claims No: 15–0295V
57. Nadara Shives, Boston, Massachusetts, Court of Federal Claims No: 15–0296V
58. Joseph Sullivan, Sarasota, Florida, Court of Federal Claims No: 15–0300V

59. Robert VanOsdol, Dallas, Texas, Court of Federal Claims No: 15–0303V
60. Melissa Intini on behalf of Vanni Mae Intini, Fort Bragg, North Carolina, Court of Federal Claims No: 15–0304V
61. Erich Micheal Gram, Huntersville, North Carolina, Court of Federal Claims No: 15–0305V
62. Edward M. Haney, San Pablo, California, Court of Federal Claims No: 15–0310V
63. Charles Rohrer, Cedar Rapids, Iowa, Court of Federal Claims No: 15–0311V
64. Jovan Ragia, Dallas, Texas, Court of Federal Claims No: 15–0312V
65. Karen Ryf, Oshkosh, Wisconsin, Court of Federal Claims No: 15–0313V
66. Jaymeeni Patel, Atlanta, Georgia, Court of Federal Claims No: 15–0318V
67. Angela Waters, Seneca, South Carolina, Court of Federal Claims No: 15–0320V
68. Beatrice Thomure, Boston, Massachusetts, Court of Federal Claims No: 15–0322V
69. Annmarie Auer, Boston, Massachusetts, Court of Federal Claims No: 15–0323V
70. Sara Olivia Cain, Raleigh, North Carolina, Court of Federal Claims No: 15–0325V
71. Nicholas Reinking and Hilary Katherine Reinking on behalf of M. R., Phoenix, Arizona, Court of Federal Claims No: 15–0326V
72. Philip Power and April Power on behalf of C. P., Cary, North Carolina, Court of Federal Claims No: 15–0327V

[FR Doc. 2015–09602 Filed 4–23–15; 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 (5 U.S.C. App.), 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, Epigenetics, Heparins, and Neurologic Disorders.

Date: May 1, 2015.

Time: 1:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Suzan Nadi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5217B, MSC 7846, Bethesda, MD 20892, 301–435–1259, *nadis@csr.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, PAR–12–138: NHLBI Systems Biology Collaborations.

Date: May 18–19, 2015.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Ai-Ping Zou, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118, MSC 7814, Bethesda, MD 20892, 301–408–9497, *zouai@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel, PAR–12–138: NHLBI Systems Biology Collaborations.

Date: May 18–19, 2015.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Katherine M Malinda, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4140, MSC 7814, Bethesda, MD 20892, 301–435–0912, *Katherine_Malinda@csr.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: April 20, 2015.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–09500 Filed 4–23–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Advancing Translational Sciences Special Emphasis Panel LRP.

Date: June 2–3, 2015.

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

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Barbara J. Nelson, Ph.D., Scientific Review Officer, Office of Scientific Review, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health, 6701 Democracy Blvd., Democracy 1, Room 1080, Bethesda, MD 20892–4874, 301–435–0806, *nelsonbj@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.350, B—Cooperative Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: April 20, 2015.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–09502 Filed 4–23–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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 Inherited Disease Research Access Committee.

Date: May 7, 2015.