MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: *PCAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Background: Section 503A of the FD&C Act (21 U.S.C. 353a) describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist or licensed physician to be exempt from the following three sections of the FD&C Act: (1) Section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice (CGMP)); (2) section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use); and (3) section 505 (21 U.S.C. 355) (concerning the approval of human drug products under new drug applications (NDAs) or abbreviated new drug applications (ANDAs)).

One of the conditions that must be satisfied to qualify for the exemptions under section 503A of the FD&C Act is that a bulk drug substance (active pharmaceutical ingredient) used in a compounded drug product must meet one of the following criteria: (1) Complies with the standards of an applicable United States Pharmacopoeia (USP) or National Formulary monograph, if a monograph exists, and the USP chapter on pharmacy compounding; (2) if an applicable monograph does not exist, is a component of a drug approved by the Secretary of Health and Human Services (the Secretary); or (3) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, appears on a list (the ''section 503A bulk drug substances list'') developed by the Secretary through regulations issued by the Secretary (see section 503A(b)(1)(A)(i) of the FD&C Act).

FDA will discuss with the committee drugs proposed for inclusion on the section 503A bulk drug substances list.

Agenda: The committee intends to discuss six bulk drug substances nominated for inclusion on the section 503A bulk drug substances list. FDA intends to discuss the following nominated bulk drug substances: Chrysin, cesium chloride, sodium dichloroacetate, pyruvic acid, tea tree oil, and 2,3-Dimercapto-1-propanesulfonic acid (DMPS). The nominators of these substances will be invited to make a short presentation supporting the nomination. During the afternoon session, the committee will receive updates on certain issues to follow up on discussions from previous meetings, including the option for obtaining access to investigational new drugs under expanded access.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before June 15, 2016. Oral presentations from the public will be scheduled between approximately 9:30 a.m. and 9:40 a.m., 10:35 a.m. and 10:45 a.m., 11:40 a.m. and 11:50 a.m., 2:15 p.m. and 2:25 p.m., 3:20 p.m. and 3:30 p.m., and 4:40 p.m. and 4:50 p.m. Those individuals interested in making formal oral presentations should notify Cindy Hong and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before June 10, 2016. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by June 13, 2016.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Cindy Hong at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 31, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–13169 Filed 6–2–16; 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 (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.

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 April 1, 2016, through April 30, 2016. 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 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.

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 08N146B, Rockville, MD 20857; (301) 443–6593, or visit our Web site at: *http://www.hrsa.gov/vaccinecompensation/index.html.*

Dated: May 26, 2016.

James Macrae,

Acting Administrator.

List of Petitions Filed

1. Christopher Stephen Fennell; Sun City West, Arizona; Court of Federal Claims No: 16–0413V
2. Willie Johnson; Dublin, Georgia; Court of Federal Claims No: 16–0415V
3. Maria Villanueva; Utuado, Puerto Rico; Court of Federal Claims No: 16–0416V
4. Laura Friedel; Woodstock, Illinois; Court of Federal Claims No: 16–0417V
5. Kathleen Mosier; Akron, Ohio; Court of Federal Claims No: 16–0418V
6. Christina Osenbach and Bryan Osenbach on behalf of B. O.; Boston, Massachusetts; Court of Federal Claims No: 16–0419V
7. Meredith Pyers; Columbus, Ohio; Court of Federal Claims No: 16–0421V
8. Alexandria Skeens; Granville, Ohio; Court of Federal Claims No: 16–0423V
9. Marsha Crawford; Paris, Kentucky; Court of Federal Claims No: 16–0428V
10. Edward McMahon; Tucson, Arizona; Court of Federal Claims No: 16–0429V
11. Kristina Raab on behalf of J. R.; San Diego, California; Court of Federal Claims No: 16–0431V
12. Pella Parker; Los Angeles, California; Court of Federal Claims No: 16–0433V
13. Michele Jacob and Craig Jacob on behalf of Ryan Jacob; New York, New York; Court of Federal Claims No: 16–0434V
14. Jason Guido on behalf of D. G.; Rochester, Pennsylvania; Court of Federal Claims No: 16–0435V
15. Carl L. Anderson; Baltimore, Maryland; Court of Federal Claims No: 16–0436V
16. Kelsi Amen; Grand Island, Nebraska; Court of Federal Claims No: 16–0437V
17. Martin Rausch; Avery, North Carolina; Court of Federal Claims No: 16–0438V
18. Timothy Koller; Neenah, Wisconsin; Court of Federal Claims No: 16–0439V
19. Christian Geideman and Erinn Geideman on behalf of H. G. G.; Menlo Park, California; Court of Federal Claims No: 16–0443V
20. Vilma Espada Cubano; San Juan, Puerto Rico; Court of Federal Claims No: 16–0444V
21. Regina Murrell; Jackson, Mississippi; Court of Federal Claims No: 16–0445V
22. Kristen Bell; Alpharetta, Georgia; Court of Federal Claims No: 16–0450V
23. Lorraine Sofia; Lyndhurst, New Jersey; Court of Federal Claims No: 16–0452V
24. Arlene Sandman; Boston, Massachusetts; Court of Federal Claims No: 16–0453V
25. Frederick Green; Newport, Rhode Island; Court of Federal Claims No: 16–0454V
26. Linda Commesso; Boston, Massachusetts; Court of Federal Claims No: 16–0455V
27. Isaac Watson; Indianapolis, Indiana; Court of Federal Claims No: 16–0456V
28. Patricia Swanson; Beverly, Massachusetts; Court of Federal Claims No: 16–0457V
29. Betty D. Backman; Manhattan, Kansas; Court of Federal Claims No: 16–0458V
30. Sandra E. Williams on behalf of Richard Williams, Deceased;

Surprise, Arizona; Court of Federal Claims No: 16–0459V
31. Linda K. Russell; Tampa, Florida; Court of Federal Claims No: 16–0460V
32. Steven Patton; Vienna, Virginia; Court of Federal Claims No: 16–0461V
33. Scott Cipa; Vienna, Virginia; Court of Federal Claims No: 16–0462V
34. Jessica Buckingham; New Castle, Delaware; Court of Federal Claims No: 16–0463V
35. Mette Rose and Soren Rose Kjaer on behalf of F. R. K.; New York, New York; Court of Federal Claims No: 16–0465V
36. Mette Rose and Soren Rose Kjaer on behalf of M. R. K.; New York, New York; Court of Federal Claims No: 16–0466V
37. Victoria Pusateri; Southgate, Michigan; Court of Federal Claims No: 16–0467V
38. Nathaniel Paul; Fairfax, Virginia; Court of Federal Claims No: 16–0468V
39. Rebecca S. Melgares; Milwaukee, Wisconsin; Court of Federal Claims No: 16–0470V
40. Arthur L. Trollinger; Graham, North Carolina; Court of Federal Claims No: 16–0473V
41. Tracy E. Carrozza; Princeton, New Jersey; Court of Federal Claims No: 16–0474V
42. Allen O. Cabansag; Spring Valley, California; Court of Federal Claims No: 16–0475V
43. Luciana Desa; Washington, District of Columbia; Court of Federal Claims No: 16–0476V
44. Deborah Tebault on behalf of J. T.; Phoenix, Arizona; Court of Federal Claims No: 16–0478V
45. Stephen Vasas; Ann Arbor, Michigan; Court of Federal Claims No: 16–0479V
46. Theresa Hibbs; Shepherdsville, Kentucky; Court of Federal Claims No: 16–0481V
47. Stephanie Gilbert on behalf of P. L.; Vienna, Virginia; Court of Federal Claims No: 16–0484V
48. Sonya Tabor; Beverly Hills, California; Court of Federal Claims No: 16–0485V
49. The Estate of Frank Lee Kapp, Jr., Deceased; Salisbury, North Carolina; Court of Federal Claims No: 16–0487V
50. Leslie Lewis; Lexington, South Carolina; Court of Federal Claims No: 16–0488V
51. Christine Benshoff; Orwigsburg, Pennsylvania; Court of Federal Claims No: 16–0489V
52. Robert Hearn; Jackson, Mississippi; Court of Federal Claims No: 16–0493V
53. John Neukom; Normangee, Texas; Court of Federal Claims No: 16–0495V
54. Heather Wright on behalf of B. W.; Washington, District of Columbia; Court of Federal Claims No: 16–0498V
55. Julian Henley; Scottsbluff, Nebraska; Court of Federal Claims No: 16–0499V
56. Misty Pasco on behalf of M. P.; Phoenix, Arizona; Court of Federal Claims No: 16–0500V
57. Janis Pool; Lawrence, Kansas; Court of Federal Claims No: 16–0503V
58. Jeffrey A. Bales; Greensboro, North Carolina; Court of Federal Claims No: 16–0505V
59. Terry Bartee; Antioch, California; Court of Federal Claims No: 16–0506V
60. Linda Barton; Lancaster, Pennsylvania; Court of Federal Claims No: 16–0508V
61. Richard George Laux; Farmington Hills, Michigan; Court of Federal Claims No: 16–0509V
62. Judith A. Pannick; Flint, Michigan; Court of Federal Claims No: 16–0510V
63. Laura Kerrin; Philadelphia, Pennsylvania; Court of Federal Claims No: 16–0511V
64. Rev. Andrew Thomas Moody on behalf of E. G. M.; Houston, Texas; Court of Federal Claims No: 16–0513V
65. James Ritchie; Ponte Vedra Beach, Florida; Court of Federal Claims No: 16–0514V
66. Thomas Smith; Weston, West Virginia; Court of Federal Claims No: 16–0520V
67. Shahid Mahroof; Stony Brook, New York; Court of Federal Claims No: 16–0521V
68. Stephanie Smith; Allentown, Pennsylvania; Court of Federal Claims No: 16–0522V
69. Monika Piatek on behalf of N. P.; Chicago, Illinois; Court of Federal Claims No: 16–0524V
70. Patricia Rubio; Bedford, New Hampshire; Court of Federal Claims No: 16–0525V
71. Frederick Morrison; Gulf Breeze, Florida; Court of Federal Claims No: 16–0526V
72. Gary Schilling; Boston, Massachusetts; Court of Federal Claims No: 16–0527V
73. Tiffany Harris on behalf of A. H.; Boston, Massachusetts; Court of Federal Claims No: 16–0528V
74. Lianna Roberts; Boston, Massachusetts; Court of Federal Claims No: 16–0529V
75. Jennifer Young; Canton, Michigan; Court of Federal Claims No: 16–0530V
76. Scott Pudalov; Boulder, Colorado; Court of Federal Claims No: 16–0532V
77. Tracy Butler; Denver, Colorado; Court of Federal Claims No: 16–0534V

[FR Doc. 2016–13073 Filed 6–2–16; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

Karen M. D'Souza, Ph.D., University of Chicago: Based on the report of an investigation conducted by the University of Chicago (UC) and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Karen M. D'Souza, former Research Professional Associate, Department of Surgery, UC, engaged in research misconduct in research supported by National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH), grants K08 HL081472 and R01 HL107949.

ORI found that falsified and/or fabricated data were included in the following one (1) funded NIH grant, two (2) publications, two (2) posters, and one (1) presentation:

- R01 HL107949–01
- *J Biol Chem.* 285(18):13748–60, 2010 Apr 30 (hereafter referred to as ''*JBC* 2010'')
- *J Biol Chem.* 286(17):15507–16, 2011 Apr 29 (hereafter referred to as ''*JBC* 2011'')
- Gordon Conference 2006 poster: ''Regulation of Myocardial β-Adrenergic Receptor Signaling By Protein Kinase C'' (hereafter referred to as ''GC2006'')
- Huggins 2010 poster: Gαq-mediated activation of GRK2 by mechanical stretch in cardiac myocytes; the role of protein kinase C'' (hereafter referred to as ''HP2010'')
- Cardiac Research Day 2009 presentation: ''Regulation of G protein-coupled receptor signaling by mechanical stretch in cardiac myocytes'' (hereafter referred to as ''CR2009'')

ORI found that Respondent reused and falsely relabeled and/or falsely spliced Western blot images, falsified