

- Permitting certain prior approval manufacturing supplements to be resubmitted as “Supplement—Changes Being Effected in 30 days.”

- Permitting comparability protocols to be submitted as protocols without substantial data in an INAD file.

- Developing a process where supporting information for pre-submission conferences and INAD protocols without data submissions can be submitted early.

- Exploring the feasibility of pursuing statutory revisions that may modify the current requirements that the use of multiple new animal drugs in the same medicated feed be subject to an approved application.

- Exploring the feasibility of pursuing statutory revisions that may expand the use of conditional approvals to other appropriate categories of new animal drug applications.

FDA has published a number of reports that provide useful background on ADUFA I, ADUFA II, and ADUFA III. ADUFA-related **Federal Register** notices, guidances, legislation, performance reports, and financial reports and plans can be found at: <http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/default.htm>.

III. Meeting Information

A. Meeting Format

In general, the meeting format will include presentations by FDA followed by an open public comment period. Registered speakers for the open public comments will be grouped and scheduled in advance of the meeting based on their affiliation (scientific and academic experts/veterinary professionals, representatives of consumer advocacy groups, and the regulated industry) and timing of registration. FDA presentations are planned from 9 a.m. until 10 a.m. The open public comment portion of the meeting for registered and scheduled speakers is planned to begin at 10 a.m. An opportunity for additional open public comments from meeting attendees will commence following the registered presentations, if time permits.

FDA policy issues are beyond the scope of these reauthorization discussions. Accordingly, the presentations should focus on process enhancements and funding issues, not on policy issues.

B. Meeting Questions

Please consider the following questions for this meeting:

1. What is your assessment of the overall performance of the ADUFA III program thus far?

2. What aspects of ADUFA should be retained, changed, or discontinued to further strengthen and improve the program?

C. Registration

If you wish to attend and/or present at the meeting, please register by email to cvmadufa@fda.hhs.gov by May 4, 2016. Your email should contain complete contact information for each attendee, including name, title, affiliation, address, email, and phone number. Also, please self-identify as a member of one of the following stakeholder categories: Scientific or academic experts; veterinary professionals; patients and consumer advocacy groups; or the regulated industry and whether you are requesting a scheduled presentation. Registration is free and available on a first-come, first-served basis. Early registration is recommended since seating is limited. FDA may limit the number of participants from each organization based on space constraints. Registrants will receive confirmation once their registrations are accepted. Onsite registration on the day of the public meeting will be based on space availability. FDA will try to accommodate all persons who wish to make a presentation. The time allotted for presentations may depend on the number of persons who wish to speak.

If you need special accommodations due to a disability, please contact Cassie Ravo (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

D. Transcripts

Please be advised that as soon as the transcript is available, it will be accessible at <http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/ucm042891.htm>. It may be viewed at the Division of Dockets Management (see **ADDRESSES**). A transcript will also be made available in either hard copy or on CD-ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at www.fda.gov.

Dated: April 12, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-09148 Filed 4-19-16; 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 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 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 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 “[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, 2016, through March 31, 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.

Dated: April 14, 2016.

James Macrae,
Acting Administrator.

List of Petitions Filed

1. Nina Kleinberg, Holyoke, Massachusetts, Court of Federal Claims No: 16-0287V
2. Mary Agresti, Henderson, Nevada, Court of Federal Claims No: 16-0290V
3. Gail M. Schrank, Sussex, Wisconsin, Court of Federal Claims No: 16-0292V
4. Yolanda Cartagena, Wareham, Massachusetts, Court of Federal Claims No: 16-0293V
5. Charles A. Hall, Ph.D., Greensboro, North Carolina, Court of Federal Claims No: 16-0294V
6. Angel Villa, Dallas, Texas, Court of Federal Claims No: 16-0295V
7. Robert W. Montague, Chattanooga, Tennessee, Court of Federal Claims No: 16-0298V
8. Joshua Howard, Waupun, Wisconsin, Court of Federal Claims No: 16-0299V
9. Charles Moore, Southside, Alabama, Court of Federal Claims No: 16-0300V
10. Judith Marjorie Tipton, Asheville, North Carolina, Court of Federal Claims No: 16-0303V
11. Maya Sandoval, Oakland, California, Court of Federal Claims No: 16-0304V
12. Ronald Kass, Stockton, California, Court of Federal Claims No: 16-0305V
13. Heidi Domke, Baltimore, Maryland, Court of Federal Claims No: 16-0307V
14. Alan L. Jones, Bradenton, Florida, Court of Federal Claims No: 16-0308V
15. Patricia Zuckerman, Toms River, New Jersey, Court of Federal Claims No: 16-0311V
16. Kristin Denbow, St. Louis, Missouri, Court of Federal Claims No: 16-0312V
17. Paula Absolon, Dallas, Texas, Court of Federal Claims No: 16-0313V
18. Don Knobbe, St. Louis, Missouri, Court of Federal Claims No: 16-0315V
19. Jessica R. Martin on behalf of K.M., Thomasville, North Carolina, Court of Federal Claims No: 16-0318V
20. Jewel Dailey, Canastota, New York, Court of Federal Claims No: 16-0319V
21. Christine Miners, Sarasota, Florida, Court of Federal Claims No: 16-0320V
22. Phillip Herrera, Waupun, Wisconsin, Court of Federal Claims No: 16-0321V
23. Diane Chandler, Boston, Massachusetts, Court of Federal Claims No: 16-0322V
24. Christine Reynolds, Boston, Massachusetts, Court of Federal Claims No: 16-0323V
25. Mark Clement and Shannon Clement on behalf of J.C., Boston, Massachusetts, Court of Federal Claims No: 16-0324V
26. Robert Raiche, Boston, Massachusetts, Court of Federal Claims No: 16-0325V
27. Eric Reynolds, Flint, Michigan, Court of Federal Claims No: 16-0330V
28. Jerry Santoni, Phoenix, Arizona, Court of Federal Claims No: 16-0331V
29. Dorothy Sicard on behalf of S.S., Phoenix, Arizona, Court of Federal Claims No: 16-0332V
30. Shelly M. Pinckard, Pensacola, Florida, Court of Federal Claims No: 16-0333V
31. Sarah Fields, Edwards AFB, California, Court of Federal Claims No: 16-0335V
32. Deborah Gilbert, Dresher, Pennsylvania, Court of Federal Claims No: 16-0337V
33. Davika Lochan, Dresher, Pennsylvania, Court of Federal Claims No: 16-0338V
34. Jonathan Catrow, Edgewater, Maryland, Court of Federal Claims No: 16-0339V
35. Hilda Almanzar, Hainesport, New Jersey, Court of Federal Claims No: 16-0340V
36. Paul Hillen, Dresher, Pennsylvania, Court of Federal Claims No: 16-0341V
37. Stephen Schmidt, Dresher, Pennsylvania, Court of Federal Claims No: 16-0342V
38. Heather Gillotti, Dresher, Pennsylvania, Court of Federal Claims No: 16-0343V
39. Candace L. Holmes, Mocksville, North Carolina, Court of Federal Claims No: 16-0349V

40. John Gowan Wellesley, Massachusetts, Court of Federal Claims No: 16–0350V
41. Katherine Irvin on behalf of Cuba Woods, Culver City, California, Court of Federal Claims No: 16–0351V
42. Dufhane Hyde, Sr. on behalf of Dufhane Hyde, Jr., Deceased, Bloomfield, Connecticut, Court of Federal Claims No: 16–0354V
43. James Hooper, Dresher, Pennsylvania, Court of Federal Claims No: 16–0355V
44. Russell Burden, Boston, Massachusetts, Court of Federal Claims No: 16–0359V
45. John Dakota Jackson, Spokane, Washington, Court of Federal Claims No: 16–0361V
46. Martha Worlein, Wichita, Kansas, Court of Federal Claims No: 16–0364V
47. Stephen Knowles, McLean, Virginia, Court of Federal Claims No: 16–0365V
48. Shelly Norris, Sarasota, Florida, Court of Federal Claims No: 16–0366V
49. Sophia Herrera, Dallas, Texas, Court of Federal Claims No: 16–0372V
50. Cori Marshall, Boise, Idaho, Court of Federal Claims No: 16–0373V
51. Larry Gordon, Limon, Colorado, Court of Federal Claims No: 16–0374V
52. Debra Baker, Baraboo, Wisconsin, Court of Federal Claims No: 16–0375V
53. Carolyn Wagner, Beverly Hills, California, Court of Federal Claims No: 16–0377V
54. Roger Schurg, Frostburg, Maryland, Court of Federal Claims No: 16–0378V
55. Lisa Applegate, Beverly Hills, California, Court of Federal Claims No: 16–0379V
56. Marlene Cimon, Dresher, Pennsylvania, Court of Federal Claims No: 16–0380V
57. Rebecca Kemak, Phoenix, Arizona, Court of Federal Claims No: 16–0381V
58. Maria Del Pilar Varela-Avila, Dallas, Texas, Court of Federal Claims No: 16–0382V
59. Deborah M. Williamson, Pittsburgh, Pennsylvania, Court of Federal Claims No: 16–0384V
60. Thomas Tutt, Albuquerque, New Mexico, Court of Federal Claims No: 16–0385V
61. Scott Valeen, Washington, District of Columbia, Court of Federal Claims No: 16–0390V
62. Paulette Terhune on behalf of A. T. T., Coral Springs, Florida, Court of Federal Claims No: 16–0393V

63. Jennifer Wolf-Lecy, Dallas, Texas, Court of Federal Claims No: 16–0406V
64. Sonia Bell, Chicago, Illinois, Court of Federal Claims No: 16–0407V
65. Seth Fruge and Christina Majesty on behalf of Reed Fruge, New Orleans, Louisiana, Court of Federal Claims No: 16–0410V
66. Christopher Diane Lewis, Dallas, Texas, Court of Federal Claims No: 16–0411V
67. Debra Bostwick-Kenkel, Beverly Hills, California, Court of Federal Claims No: 16–0412V

[FR Doc. 2016–09172 Filed 4–19–16; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Advisory Group on Prevention, Health Promotion, and Integrative and Public Health

AGENCY: Office of the Secretary, Office of the Assistant Secretary for Health, Office of the Surgeon General of the United States Public Health Service, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In accordance with Section 10(a) of the Federal Advisory Committee Act, Public Law 92–463, as amended (5 U.S.C. App.), notice is hereby given that a meeting is scheduled for the Advisory Group on Prevention, Health Promotion, and Integrative and Public Health (the “Advisory Group”). This meeting will be open to the public. Information about the Advisory Group and the agenda for this meeting can be obtained by accessing the following Web site: <http://www.surgeongeneral.gov/priorities/prevention/advisorygrp/advisory-group-meetings.html>.

DATES: The meeting will be held on May 9, 2016, from 8:45 a.m. to 5:00 p.m. EST—May 10, 2016, from 8:45 a.m. to 1:00 p.m. EST.

ADDRESSES: This meeting will be held at the CDC Washington Office, Room 9000, 395 E Street SW., Washington, DC 20201. Space to accommodate public in-person attendance is very limited. Therefore, arrangements are being made for access to the meeting to be made available by teleconference. Teleconference information will be published closer to the meeting date at: <http://www.surgeongeneral.gov/priorities/prevention/advisorygrp/advisory-group-meetings.html>. Individuals planning to attend the meeting by teleconference must register. The registration procedure is included

in this notice under Supplementary Information.

FOR FURTHER INFORMATION CONTACT: Office of the Surgeon General, U.S. Department of Health and Human Services, 200 Independence Ave. SW., Washington, DC 20201; 202–205–9517, npcsupport@cdc.gov.

SUPPLEMENTARY INFORMATION: The Advisory Group is a non-discretionary federal advisory committee that was initially established under Executive Order 13544, dated June 10, 2010, to comply with the statutes under Section 4001 of the Patient Protection and Affordable Care Act, Public Law 111–148. The Advisory Group was terminated on September 30, 2012, by Executive Order 13591, dated November 23, 2011. Authority for the Advisory Group to be re-established was given under Executive Order 13631, dated December 7, 2012. Authority for the Advisory Group to continue to operate until September 30, 2017, was given under Executive Order 13708, dated September 30, 2015.

The Advisory Group was established to assist in carrying out the mission of the National Prevention, Health Promotion, and Public Health Council (the Council). The Advisory Group provides recommendations and advice to the Council.

It is authorized for the Advisory Group to consist of no more than 25 non-federal members. The Advisory Group currently has 21 members who were appointed by the President. The membership includes a diverse group of licensed health professionals, including integrative health practitioners who have expertise in (1) worksite health promotion; (2) community services, including community health centers; (3) preventive medicine; (4) health coaching; (5) public health education; (6) geriatrics; and (7) rehabilitation medicine.

A meeting description and relevant materials will be published closer to the meeting date at: <http://www.surgeongeneral.gov/priorities/prevention/advisorygrp/advisory-group-meetings.html>. Members of the public have the opportunity to participate in the meeting and/or provide comments via teleconference to the Advisory Group on May 9–10, 2016. Public comment will be limited to 3 minutes per speaker. Individuals who wish to participate in the meeting and/or provide comments via teleconference must register by 12:00 p.m. EST on April 25, 2016. In order to register, individuals must send their full name and affiliation via email to npcsupport@cdc.gov. Individuals who need special