

Silver Spring, MD 20993-0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. Send two self-addressed adhesive labels to assist the office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Robert H. King, Sr., Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 4150, Silver Spring, MD 20993-0002, 301-796-1242; or Christopher Joneckis, Center for Biologics Evaluation and Research (HFM-25), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-0373.

Regarding the ICH: Michelle Limoli, Office of International Programs (HFG-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4480.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of

pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In October 2009, the ICH Steering Committee agreed that a draft guidance entitled "Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 12: Analytical Sieving General Chapter" should be made available for public comment. The draft guidance is the product of the Q4B Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Q4B Expert Working Group.

The draft guidance provides the specific evaluation results from the ICH Q4B process for the Analytical Sieving General Chapter harmonization proposal originating from the three-party PDG. This draft guidance is in the form of an annex to the core ICH Q4B guidance. Once finalized, the annex will provide guidance to assist industry and regulators in the implementation of the specific topic evaluated by the ICH Q4B process.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit a single copy of electronic comments or two paper copies of any

mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.regulations.gov>, <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>.

Dated: December 11, 2009.

David Horowitz,

Assistant Commissioner for Policy.

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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 his 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 which 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 the Secretary publish in the **Federal Register** a notice of each petition filed. Set forth below is a list of petitions received by HRSA on January 5, 2009, through March 30, 2009.

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 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.

This notice will also serve as the special master's invitation to all interested persons to 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 Vaccine Injury Compensation Program, 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.

List of Petitions

1. Tracy and Edward Roman on behalf of Chase Roman, Philadelphia, Pennsylvania. *Court of Federal Claims Number: 09-0001V.*
2. Michelle and Waleed Moujaes on behalf of Dimitri Moujaes, Dublin, Ohio. *Court of Federal Claims Number: 09-0002V.*
3. Annette and Matt Flynn on behalf of Nathan Flynn, Kenosha, Washington. *Court of Federal Claims Number: 09-0009V.*
4. Brenda and Daniel Klein on behalf of Kara Quinn Klein, McMurray, Pennsylvania. *Court of Federal Claims Number: 09-0010V.*
5. Nelly and Leon Huppert on behalf of Zachary Huppert, Garden City, New York. *Court of Federal Claims Number: 09-0011V.*
6. James Burghardt, Staten Island, New York. *Court of Federal Claims Number: 09-0012V.*
7. Benjamin Jahanbani, Riverside, California. *Court of Federal Claims Number: 09-0019V.*
8. Glinda Morse on behalf of Kaden Morse, Crawfordville, Florida. *Court of Federal Claims Number: 09-0023V.*
9. Amy and Evan and Tyler Frey on behalf of Frederick Frey, Jr., Deceased, Baton Rouge, Louisiana. *Court of Federal Claims Number: 09-0026V.*

10. Kimberly Hicks on behalf of Chasen Hicks, Baytown, Texas. *Court of Federal Claims Number: 09-0028V.*

11. Deborah and Jack Breard on behalf of Reneau Breard, Garden City, New York. *Court of Federal Claims Number: 09-0029V.*

12. Cynthia Lilley on behalf of Robert Lilley, Nashville, Tennessee. *Court of Federal Claims Number: 09-0031V.*

13. Jacqueline and Mark Smith on behalf of Kyler J. Smith, Palm Harbor, Florida. *Court of Federal Claims Number: 09-0032V.*

14. Ronald R. Leyland, Greensburg, Pennsylvania. *Court of Federal Claims Number: 09-0033V.*

15. Elliott M. Leake, Raleigh, North Carolina. *Court of Federal Claims Number: 09-0034V.*

16. Amy Crutchfield, New York, New York. *Court of Federal Claims Number: 09-0039V.*

17. Theresa and Mark Eichinger on behalf of Samantha Eichinger, Cedar Rapids, Iowa. *Court of Federal Claims Number: 09-0040V.*

18. Cheri A. Johnson, Coon Rapids, Minnesota. *Court of Federal Claims Number: 09-0041V.*

19. Helaine and William Searle on behalf of Cody James Searle, Prescott, Arizona. *Court of Federal Claims Number: 09-0043V.*

20. Dayna and Mike Relstab on behalf of Michael Relstab, Memphis, Tennessee. *Court of Federal Claims Number: 09-0047V.*

21. Lee Keffer, Kosovo, Serbia. *Court of Federal Claims Number: 09-0050V.*

22. Sharon Goldman, Somerville, Massachusetts. *Court of Federal Claims Number: 09-0051V.*

23. Shauna Ammendola, Ridgewood, New Jersey. *Court of Federal Claims Number: 09-0056V.*

24. Ziva Fink, St. Louis Park, Minnesota. *Court of Federal Claims Number: 09-0057V.*

25. Patricia Blow on behalf of Kenn Blow, Deceased, Faribault, Minnesota. *Court of Federal Claims Number: 09-0058V.*

26. Lauren Caro, Sunrise, Florida. *Court of Federal Claims Number: 09-0061V.*

27. Donna and John Guerra on behalf of Michael Guerra, San Antonio, Texas. *Court of Federal Claims Number: 09-0062V.*

28. Melissa and John Mark Wallace on behalf of Melodi Mae Wallace, Sandy, Utah. *Court of Federal Claims Number: 09-0065V.*

29. Julia and Thomas Canny on behalf of Christian Canny, Garden City, New York. *Court of Federal Claims Number: 09-0068V.*

30. Tserendulam and Daniel Wagner on behalf of Sarnai Wagner, Pooler,

Georgia. *Court of Federal Claims Number: 09-0069V.*

31. Angela and Andrew Rewolinski on behalf of Alexander Rewolinski, West Allis, Wisconsin. *Court of Federal Claims Number: 09-0070V.*

32. Angela and Andrew Rewolinski on behalf of Ethan Rewolinski, West Allis, Wisconsin. *Court of Federal Claims Number: 09-0071V.*

33. Catherine Guidry on behalf of Hayden Guidry, St. Francisville, Louisiana. *Court of Federal Claims Number: 09-0072V.*

34. Shannon Nelson, Schaumburg, Illinois. *Court of Federal Claims Number: 09-0073V.*

35. Dolores Holzem, Dells, Wisconsin. *Court of Federal Claims Number: 09-0076V.*

36. Jessica and R. Blake Schmutz on behalf of Dallin Blake Schmutz, Dallas, Texas. *Court of Federal Claims Number: 09-0077V.*

37. Hodan Hassan on behalf of Geni-Fadumo Farah, New Hope, Minnesota. *Court of Federal Claims Number: 09-0079V.*

38. Cheryl and Ernest Graves on behalf of Garrett Lee Graves, Fernandina Beach, Florida. *Court of Federal Claims Number: 09-0080V.*

39. Neeru Arora, Vernon Hills, Illinois. *Court of Federal Claims Number: 09-0083V.*

40. Ben D. Schultz, Sauk City, Wisconsin. *Court of Federal Claims Number: 09-0084V.*

41. Tiffany and Rodrigo Magalhaes on behalf of Christopher Magalhaes, Camp Legune, North Carolina. *Court of Federal Claims Number: 09-0085V.*

42. Sou Sou Awad on behalf of Christopher L. Varga, Phoenix, Arizona. *Court of Federal Claims Number: 09-0087V.*

43. Helen and Lloyd Barnes on behalf of Helen Therese Barnes, Omaha, Nebraska. *Court of Federal Claims Number: 09-0088V.*

44. Usamayah Danesi on behalf of Sean Danesi, Reseda, California. *Court of Federal Claims Number: 09-0090V.*

45. Rachel Campos on behalf of Alexis Campos, Bountiful, Utah. *Court of Federal Claims Number: 09-0091V.*

46. Elizabeth Pace Laderer, Glenn Cove, New York. *Court of Federal Claims Number: 09-0097V.*

47. April and Scott Sanders on behalf of Mathew Dylan Sanders, Ada, Oklahoma. *Court of Federal Claims Number: 09-0098V.*

48. Carlis James DeWese, Gambrills, Maryland. *Court of Federal Claims Number: 09-0101V.*

49. Chistina Blackfox on behalf of Victoria Nicole Blackfox, Deceased, Miami, Oklahoma. *Court of Federal Claims Number: 09-0102V.*

50. Katie and Mark Eleccion on behalf of Mark Eleccion, Napa, California. *Court of Federal Claims Number: 09-0105V.*

51. Michelle Broussard-Pacot on behalf of Cole Pacot, Rowlett, Texas. *Court of Federal Claims Number: 09-0107V.*

52. Harry Selph, Greenville, South Carolina. *Court of Federal Claims Number: 09-0110V.*

53. Radhakrishna Kukkillaya on behalf of Manorama A. Kukkillaya, Logan, West Virginia. *Court of Federal Claims Number: 09-0115V.*

54. Katie and Dan Dittman on behalf of Jolie Tess Dittman, Omaha, Nebraska. *Court of Federal Claims Number: 09-0117V.*

55. Sonya and Erik Mercado on behalf of Erik Mercado, Jr., Deceased, Austin, Texas. *Court of Federal Claims Number: 09-0120V.*

56. Kimberly Totzkay on behalf of Shelby Whale, Taylor, Michigan. *Court of Federal Claims Number: 09-0123V.*

57. Susan Johnson, Winston-Salem, North Carolina. *Court of Federal Claims Number: 09-0124V.*

58. Yin H. Mendive-Garcia and Julio Garcia on behalf of Julian A. Garcia, Richardson, Texas. *Court of Federal Claims Number: 09-0126V.*

59. Elizabeth Medina and George Barahona on behalf of Brandon Barahona, Wenonah, New Jersey. *Court of Federal Claims Number: 09-0127V.*

60. Trinity and Johnny Montgomery on behalf of Trace Montgomery, Ardmore, Oklahoma. *Court of Federal Claims Number: 09-0128V.*

61. Brianna Samsal on behalf of Michael Thomas Martin, Deceased, Newport Beach, California. *Court of Federal Claims Number: 09-0132V.*

62. Yin H. Mendive-Garcia and Julio Garcia on behalf of Julian A. Garcia, Richardson, Texas. *Court of Federal Claims Number: 09-0134V.*

63. Eura Dell Franklin, Dallas, Texas. *Court of Federal Claims Number: 09-0135V.*

64. Joseph John Dushel, Baltimore, Maryland. *Court of Federal Claims Number: 09-0138V.*

65. Jamie and Joseph Uhelsky on behalf of Caitlin Uhelsky, Middletown, New York. *Court of Federal Claims Number: 09-0140V.*

66. Limya Elshazli on behalf of Mohamed Mohamed, Dallas, Texas. *Court of Federal Claims Number: 09-0141V.*

67. Jody and James Rettig on behalf of Tristan James Rettig, Cumming, Georgia. *Court of Federal Claims Number: 09-0143V.*

68. Santhamma George, Dallas, Texas. *Court of Federal Claims Number: 09-0144V.*

69. Michelle and William Sasser on behalf of Katherine Elizabeth Sasser, Santa Rosa, California. *Court of Federal Claims Number: 09-0145V.*

70. Susan Lawson on behalf of Julia Grimes, Boca Raton, Florida. *Court of Federal Claims Number: 09-0148V.*

71. Thomas Lamb, San Francisco, California. *Court of Federal Claims Number: 09-0149V.*

72. Valerie Soto on behalf of Yvette Diaz, Las Vegas, Nevada. *Court of Federal Claims Number: 09-0150V.*

73. Ronie Fearon, South Euclid, Ohio. *Court of Federal Claims Number: 09-0151V.*

74. Lu Marie Guzman-Diaz and Hector Orellano-Diaz on behalf of Jeshua Orellano-Guzman, Napa, California. *Court of Federal Claims Number: 09-0157V.*

75. Bridget and Dusty Golden on behalf of Hailey Golden, Miami, Oklahoma. *Court of Federal Claims Number: 09-0161V.*

76. Jeremy Coe, Columbus, Nebraska. *Court of Federal Claims Number: 09-0169V.*

77. Lynn and Scott O'Brien on behalf of Davis William O'Brien, Woodstock, Georgia. *Court of Federal Claims Number: 09-0170V.*

78. Zenoria Phillips-DeLoatch on behalf of Moshella F. Roberts, Deceased, Fayetteville, North Carolina. *Court of Federal Claims Number: 09-0171V.*

79. Andrea Cortez on behalf of Renaldo Cortez, Deceased, Baycliff, Texas. *Court of Federal Claims Number: 09-0176V.*

80. Judy A. Jourden, Bradford, Pennsylvania. *Court of Federal Claims Number: 09-0177V.*

81. Jeremy Coe, Columbus, Nebraska. *Court of Federal Claims Number: 09-0178V.*

82. Debby and Dalibor Hradek on behalf of Federico Hradek, Lima, Ohio. *Court of Federal Claims Number: 09-0179V.*

83. Justin W. Gerhardt, Quantico, Virginia. *Court of Federal Claims Number: 09-0180V.*

84. Calista and Sam Bussard on behalf of James Bussard, Deceased, Spokane Valley, Washington. *Court of Federal Claims Number: 09-0191V.*

85. Dana Ionescu on behalf of Emma Ionescu, Cooper City, Florida. *Court of Federal Claims Number: 09-0192V.*

Dated: December 10, 2009.

Mary K. Wakefield,
Administrator.

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