that special controls, when combined with the general controls, will be sufficient to provide reasonable assurance of the safety and effectiveness of implanted blood access devices for hemodialysis. Thus, a manufacturer who intends to market a device of this generic type must (1) conform to the general controls of the Federal Food, Drug & Cosmetic Act (the FD&C Act), including the premarket notification requirements described in 21 CFR part 807 Subpart E, (2) address the special controls associated with implanted blood access devices for hemodialysis codified in the Code of Federal Regulations § 876.5540(b)(1), and (b)(3) obtain a substantial equivalence determination from FDA prior to marketing the device.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on implanted blood access devices for hemodialysis. 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 statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* To receive ''implanted blood access devices for hemodialysis'' you may either send an email request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1781 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; the collections of information in 21 CFR part 801 and 809 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information in 21 CFR 56.115 have been approved under OMB control number 0910–0130; and the collections of information in 21 CFR part 54 have been approved under OMB control number 0910–0396.

V. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Dated: June 25, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–15505 Filed 6–27–13; 8:45 am]

BILLING CODE 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 her 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 ''[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, 2013, through May 30, 2013. 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 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 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.

Dated: June 24, 2013.

Mary K. Wakefield,

Administrator.

List of Petitions Filed

1. James Gordon Cook, Vinita, Oklahoma, Court of Federal Claims No: 13–0309V.
2. Brian Charles Jensen, Santa Clarita, California, Court of Federal Claims No: 13–0310V.
3. Sandy Richardson on behalf of Indy Gantt, Columbus, Ohio, Court of Federal Claims No: 13–0313V.
4. Brooke Searles, Torrance, California, Court of Federal Claims No: 13–0318V.
5. Alfonso Pacheco, New Fairfield, Connecticut, Court of Federal Claims No: 13–0322V.
6. Michael and Kimberly Prater on behalf of Christian M. Prater, Sheridan, Indiana, Court of Federal Claims No: 13–0325V.
7. Earleen Bean-Sasser, Eureka, California, Court of Federal Claims No: 13–0326V.
8. Michael G. Corcoran on behalf of S.R.C., Chagrin Falls, Ohio, Court of Federal Claims No: 13–0330V.
9. Daniella Castillo and Daniel Ruiz on behalf of D.R., Coral Gables, Florida, Court of Federal Claims No: 13–0333V.
10. Isabel Terrell, Palm Beach Gardens, Florida, Court of Federal Claims No: 13–0334V.
11. Teresa N. Gore, Loris, South Carolina, Court of Federal Claims No: 13–0335V.
12. Charlise Ellis on behalf of X'Von Godwin, Brentwood, New Jersey, Court of Federal Claims No: 13–0336V.
13. Brian Randall, Ventura, California, Court of Federal Claims No: 13–0337V.
14. Amy Cain, Charleston, West Virginia, Court of Federal Claims No: 13–0342V.
15. Marva Ross, Vienna, Virginia, Court of Federal Claims No: 13–0343V.
16. Jesse Knight, Gilbert, Arizona, Court of Federal Claims No: 13–0344V.
17. Christina and Greg Schniegenberg on behalf of Morgan Schniegenberg, Napa, California, Court of Federal Claims No: 13–0347V.
18. Glynis Lee, Houston, Texas, Court of Federal Claims No: 13–0348V.
19. Cristal Bello, Baraboo, Wisconsin, Court of Federal Claims No: 13–0349V.
20. Arlene Trompczynski, Oakland, California, Court of Federal Claims No: 13–0351V.
21. Glenn C. Ryan, St. Augustine, Florida, Court of Federal Claims No: 13–0354V.
22. Stacy and William Boula on behalf of Stephanie Boula, Rochester, New York, Court of Federal Claims No: 13–0356V.
24. Terry Lee Estvold, Federal Way, Washington, Court of Federal Claims No: 13–0358V.
25. Amanda LaCroix, San Antonio, Texas, Court of Federal Claims No: 13–0359V.
26. Timothy Woody and Carmen Verdugo-Woody on behalf of V. W., Homestead, Florida, Court of Federal Claims No: 13–0366V.

[FR Doc. 2013–15535 Filed 6–27–13; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Family Life, Activity, Sun, Health, and Eating (FLASHE) Study (NCI)

Summary: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

To Submit Comments and For Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Linda Nebeling, Ph.D., Division of Cancer Control and Population Sciences, National Cancer Institute, 9609 Medical Center Drive, Room 3E102, Bethesda, MD 20892–9671 or call non-toll-free number 240–276–6855 or Email your request, including your address to: *nebelinl@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if