

U.S.C. 360f) to ban devices that present substantial deception or an unreasonable and substantial risk of illness or injury. Section 895.21 (21 CFR 895.21), on banned devices, contains certain reporting requirements. Section 895.21(d) describes the procedures for banning a device when the Commissioner of Food and Drugs (the Commissioner) decides to initiate such a proceeding. Under 21 CFR 895.22, a manufacturer, distributor, or importer of

a device may be required to submit to FDA all relevant and available data and information to enable the Commissioner to determine whether the device presents substantial deception, unreasonable and substantial risk of illness or injury, or unreasonable, direct, and substantial danger to the health of individuals.

During the past several years, there has been an average of less than one new administrative detention action per

year. Each administrative detention will have varying amounts of data and information that must be maintained. FDA's estimate of the burden under the administrative detention provision is based on FDA's discussion with one of the firms whose devices had been detained.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
800.55(g) .....	1	1	1	25	25
895.21(d)(8) and 895.22(a) .....	26	1	26	16	416
Total .....					441

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
800.55(k) .....	1	1	1	20	20

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: October 13, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2015-N-0001]

#### Office of Women's Health Update on Strategic Priorities and Initiatives for Nurses

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of meeting.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the following meeting: Office of Women's Health Update on Strategic Priorities and Initiatives. FDA staff will provide updates on strategic priorities, educational outreach, and research initiatives of interest to national organizations for nursing professionals and students.

**DATES:** The meeting will be held on November 18, 2015, 1 p.m. to 3 p.m.

**ADDRESSES:** The meeting will be held at the American Nurses Association, 8515

Georgia Ave., Suite 400, Silver Spring, MD 20910-3492.

#### FOR FURTHER INFORMATION CONTACT:

Deborah Kallgren, Office of Women's Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-9440, FAX: 301-847-8604, [deborah.kallgren@fda.hhs.gov](mailto:deborah.kallgren@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** There is no fee, but pre-registration is required. Send registration information (including name, title, organization name, address, telephone, and fax number) to Deborah Kallgren. Seating is limited to 35 participants (1 person per organization).

If you need special accommodations due to a disability, please contact Deborah Kallgren (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance.

Dated: October 13, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Advisory Commission on Childhood Vaccines; Request for Nominations for Voting Members

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Health Resources and Services Administration (HRSA) is requesting nominations to fill six vacancies on the Advisory Commission on Childhood Vaccines (ACCV). The ACCV was established by Title XXI of the Public Health Service Act (the Act), as enacted by Public Law (Pub. L.) 99-660 and as subsequently amended, and advises the Secretary of Health and Human Services (the Secretary) on issues related to implementation of the National Vaccine Injury Compensation Program (VICP).

**DATES:** The agency will receive nominations on or before December 18, 2015.

**ADDRESSES:** All nominations are to be submitted to the Director, Division of Injury Compensation Programs, Healthcare Systems Bureau (HSB),

HRSA, Parklawn Building, Room 11C-26, 5600 Fishers Lane, Rockville, Maryland 20857.

**FOR FURTHER INFORMATION CONTACT:** Ms. Annie Herzog, Principal Staff Liaison, Division of Injury Compensation Programs, HSB, HRSA, at (301) 443-6634 or email: [aherzog@hrsa.gov](mailto:aherzog@hrsa.gov).

**SUPPLEMENTARY INFORMATION:** Under the authorities that established the ACCV, the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92-463) and section 2119 of the Act, 42 U.S.C. 300aa-19, as added by Public Law 99-660 and amended, HRSA is requesting nominations for six voting members of the ACCV.

The ACCV advises the Secretary on the implementation of the VICP. The activities of the ACCV include: Recommending changes in the Vaccine Injury Table at its own initiative or as the result of the filing of a petition; advising the Secretary in implementing section 2127 of the Act regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions; surveying federal, state, and local programs and activities related to gathering information on injuries associated with the administration of childhood vaccines, including the adverse reaction reporting requirements of section 2125(b) of the Act; advising the Secretary on the methods of obtaining, compiling, publishing, and using credible data related to the frequency and severity of adverse reactions associated with childhood vaccines; consulting on the development or revision of Vaccine Information Statements; and recommending to the Director of the National Vaccine Program research related to vaccine injuries which should be conducted to carry out the VICP.

The ACCV consists of nine voting members appointed by the Secretary as follows: (1) Three health professionals, who are not employees of the United States Government, and who have expertise in the health care of children, the epidemiology, etiology, and prevention of childhood diseases, and the adverse reactions associated with vaccines, of whom at least two shall be pediatricians; (2) three members from the general public, of whom at least two shall be legal representatives (parents or guardians) of children who have suffered a vaccine related injury or death; and (3) three attorneys, of whom at least one shall be an attorney whose specialty includes representation of persons who have suffered a vaccine-related injury or death, and of whom one shall be an attorney whose specialty

includes representation of vaccine manufacturers. In addition, the Director of the National Institutes of Health, the Assistant Secretary for Health, the Director of the Centers for Disease Control and Prevention, and the Commissioner of the Food and Drug Administration (or the designees of such officials) serve as nonvoting ex officio members.

Specifically, HRSA is requesting nominations for six voting members of the ACCV representing: (1) Two health professionals, who have expertise in the health care of children, the epidemiology, etiology, and prevention of childhood diseases, and the adverse reactions associated with vaccines, of whom both shall be a pediatricians; (2) two members of the general public, of whom at least one shall be legal representative (parent or guardian) of a child who has suffered a vaccine related injury or death; and (3) two attorneys, of whom at least one shall be an attorney whose specialty includes representation of persons who have suffered a vaccine-related injury or death, and of whom one shall be an attorney whose specialty includes representation of vaccine manufacturers. Nominees will be invited to serve a 3-year term beginning the date of appointment.

The Department of Health and Human Services (HHS or Department) will consider nominations of all qualified individuals with a view to ensuring that the ACCV includes the areas of subject matter expertise noted above. Based on a recommendation made by the ACCV, the Secretary will consider having a health professional with expertise in obstetrics as the second member of the general public. Interested persons may nominate one or more qualified persons for membership on the ACCV. Nominations shall state that the nominee is willing to serve as a member of the ACCV.

ACCV members are appointed as Special Government Employees. As such, they are covered by the federal ethics rules, including the criminal conflict of interest statutes governing executive branch employees. For example, an ACCV member may be prohibited from discussions about making changes to the Vaccine Injury Table and Vaccine Information Statements for the Hepatitis B vaccine if he/she or his/her spouse owns stock valued above a certain amount in companies which manufacturer this vaccine, affecting their own pecuniary interests—including interests imputed to them. To evaluate possible conflicts of interest, potential candidates will be asked to fill out the Confidential

Financial Disclosure Report, OGE Form 450, to provide detailed information concerning financial interests, consultancies, research grants, and/or contracts that might be affected by recommendations made by the ACCV.

A nomination package should include the following information for each nominee: (1) A letter of nomination stating the name, affiliation, and contact information for the nominee, the basis for the nomination (*i.e.*, what specific attributes, perspectives, and/or skills does the individual possess that would benefit the workings of the ACCV) and the nominee's field(s) of expertise; (2) a biographical sketch of the nominee and a copy of his/her curriculum vitae; and (3) the name, address, daytime telephone number, and email address at which the nominator can be contacted.

The HHS strives to ensure that the membership of the HHS Federal Advisory Committee is fairly balanced in terms of points of view presented and the committee's function. Every effort is made to ensure that the views of women, all ethnic and racial groups, and people with disabilities are represented on HHS Federal Advisory Committees and, therefore, the Department encourages nominations of qualified candidates from these groups. The Department also encourages geographic diversity in the composition of the Committee. Appointment to this Committee shall be made without discrimination on basis of age, race, ethnicity, gender, sexual orientation, disability, and cultural, religious, or socioeconomic status.

**Jackie Painter,**

*Director, Division of the Executive Secretariat.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

[Document Identifier: OS-0990-XXXX]

### Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of