

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),