

Estimated Total Annual Burden  
Hours: 1,333.20.

#### Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov).

#### OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: [OIRA\\_SUBMISSION@OMB.EOP.GOV](mailto:OIRA_SUBMISSION@OMB.EOP.GOV).

Attn: Desk Officer for the Administration for Children and Families.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. 2012-8512 Filed 4-9-12; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0306]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Administrative Detention and Banned Medical Devices

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the

notice. This notice solicits comments on information collection for administrative detention and banned medical devices.

**DATES:** Submit either electronic or written comments on the collection of information by June 11, 2012.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

#### FOR FURTHER INFORMATION CONTACT:

Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, [Daniel.Gittleson@fda.hhs.gov](mailto:Daniel.Gittleson@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA'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 respondents, including through the use of automated collection techniques,

when appropriate, and other forms of information technology.

#### Administrative Detention and Banned Medical Devices—(OMB Control Number 0910-0114)—Extension

FDA has the statutory authority under section 304(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 334(g)) to detain during established inspections devices that are believed to be adulterated or misbranded. Section 800.55 (21 CFR 800.55), on administrative detention, includes among other things, certain reporting requirements and recordkeeping requirements. Under § 800.55(g), an applicant of a detention order must show documentation of ownership if devices are detained at a place other than that of the appellant. Under § 800.55(k), the owner or other responsible person must supply records about how the devices may have become adulterated or misbranded, in addition to records of distribution of the detained devices. These recordkeeping requirements for administrative detentions permit FDA to trace devices for which the detention period expired before a seizure is accomplished or injunctive relief is obtained.

FDA also has the statutory authority under section 516 of the FD&C Act (21 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 three 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) 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: April 3, 2012.

David Dorsey,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2012–8507 Filed 4–9–12; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2011–N–0439]

#### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Food and Drug Administration Recall Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled “Food and Drug Administration Recall Regulations” has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7726, [ila.mizrachi@fda.hhs.gov](mailto:ila.mizrachi@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** On November 28, 2011, the Agency submitted a proposed collection of information entitled “Food and Drug Administration Recall Regulations” to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a

currently valid OMB control number.

OMB has now approved the information collection and has assigned OMB control number 0910–0249. The approval expires on March 31, 2015. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: April 3, 2012.

David Dorsey,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2012–8514 Filed 4–9–12; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; as last amended at 77 FR 13613–13616 dated March 7, 2012).

This notice reflects organizational changes in the Health Resources and Services Administration. Specifically, this notice updates the functional statement for the HIV/AIDS Bureau (RV): (1) Rename the Division of Science and Policy (RVA) to the Division of Policy and Data (RVA) and update the functional statement; (2) rename the Office of Program Support (RV2) to the Office of Operations and Management (RV2); (3) rename the Division of Service Systems (RV5) to the Division of Metropolitan HIV/AIDS Programs (RV5)

and update the function statement; (4) establish the Division of State HIV/AIDS Programs (RVD); (5) rename the Division of Community Based Programs (RV6) to the Division of Community HIV/AIDS Programs (RV6); and rename the Division of Training and Technical Assistance (RV7) to the Division of HIV/AIDS Training and Capacity Development (RV7) and update the functional statement.

#### Chapter RV—HIV/AIDS Bureau

##### Section RV–10, Organization

Delete in its entirety and replace with the following:

The HIV/AIDS Bureau (RV) is headed by the Associate Administrator, HIV/AIDS Bureau (HAB), who reports directly to the Administrator, Health Resources and Services Administration. HAB includes the following components:

- (1) Office of the Associate Administrator (RV);
- (2) Office of Operations and Management (RV2);
- (3) Division of Policy and Data (RVA);
- (4) Division of Metropolitan HIV/AIDS Programs (RV5);
- (5) Division of State HIV/AIDS Programs (RVD);
- (6) Division of Community HIV/AIDS Programs (RV6); and
- (7) Division of HIV/AIDS Training and Capacity Development (RV7).

##### Section RV–20, Functions

(1) Delete the functional statement for the HIV/AIDS Bureau (RV) and replace in its entirety.

Office of the Associate Administrator (RV)

The Office of the Associate Administrator provides leadership and direction for the HIV/AIDS programs and activities of the Bureau and