

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Participant Entry Survey .....	504,279	168,093	1	.25	42,023
Participant Exit Survey .....	551,847	183,949	1	.50	91,975
Performance reporting system data form—grantees .....	951	317	2	30	19,020
Performance reporting system data form—subawardees ...	5,883	1,961	2	14	54,908

*Estimated Total Annual Burden Hours:* 207,926

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington, DC 20201, Attn: OPRE Reports Clearance Officer. Email address: [OPREinfocollection@acf.hhs.gov](mailto:OPREinfocollection@acf.hhs.gov). All requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

**Robert Sargis**

*Reports Clearance Officer.*

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**BILLING CODE 4184-37-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

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

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by May 11, 2016.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0114. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Administrative Detention and Banned Medical Devices—21 CFR 800.55(g)(1) and (g)(2), 800.55(k), 895.21(d), and 895.22; 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 the firms whose devices had been detained.

In the **Federal Register** of October 19, 2015 (80 FR 63232), FDA published a 60-day notice requesting public

comment on the proposed collection of information. No comments were received.

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: April 5, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket Nos. FDA-2012-N-0564, FDA-2015-N-0797, FDA-2012-N-0021, FDA-2012-N-0280, FDA-2007-D-0372, FDA-2014-D-0044]

**Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. **FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, *PRAStaff@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for

each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>. 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.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Labeling of Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act .....	0910-0642	2/28/2019
Foreign Supplier Verification Programs for Importers of Food for Humans and Animals .....	0910-0752	2/28/2019
Substances Generally Recognized as Safe: Notification Procedure .....	0910-0342	3/31/2019
Financial Disclosure by Clinical Investigators .....	0910-0396	3/31/2019
Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act .....	0910-0635	3/31/2019
Exempt Infant Formula Production: Current Good Manufacturing Practices (CGMPs), Quality Control Procedures, Conduct of Audits, and Records .....	0910-0811	3/31/2019