

participants and entered into RAPTER; and (7) Video recordings of coaching sessions: Collection of data on the interaction between the coaches and participants.

A second follow-up survey will be administered approximately 21 months

after random assignment. This data collection activity will be included under a separate OMB submission.

*Respondents:* Program staff and individuals enrolled in the Evaluation of Employment Coaching for TANF and Other Low-Income Populations.

Program staff may include coaches, case managers, workshop instructors, job developers, supervisors, and managers. All participants will be able to opt out of participating in the data collection activities.

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
Baseline data collection—study participants .....	6,000	2,000	1	0.33	660
Baseline data collection—staff .....	60	20	100	0.33	660
First follow-up survey .....	2,400	800	1	1	800
Semi-structured staff interviews .....	66	22	1	1.5	33
Staff survey .....	48	16	1	0.75	12
In-depth participant interviews .....	24	8	1	2.5	20
Staff reports of program service receipt .....	30	10	5,200	0.03	1,560
Video recordings of coaching sessions .....	27	9	10	0.10	9

*Estimated Total Annual Burden Hours:* 3,754.

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.

**Mary Jones,**  
*ACF/OPRE Certifying Officer.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2016-N-4620]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices; Reports of Corrections and Removals**

**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 July 26, 2017.

**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 0910-0359. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD

20852, 301-796-8867, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@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.

**Medical Devices; Reports of Corrections and Removals—21 CFR Part 806**

**OMB Control Number 0910-0359—Extension**

FDA is requesting approval for the collection of information regarding reports of corrections and removals required under part 806 (21 CFR part 806), which implements section 519(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360i(g)), as amended by the Food and Drug Modernization Act of 1997 (FDAMA) (Pub. L. 105-115). A description of the information collection requirements are provided as follows:

Under § 806.10 (21 CFR 806.10), within 10 working days of initiating any action to correct or remove a device to reduce a risk to health posed by the device or to remedy a violation of the FD&C Act caused by the device that may present a risk to health, device manufacturers or importers must submit a written report to FDA of the correction or removal.

Under § 806.20(a), device manufacturers or importers that initiate a correction or removal that is not required to be reported to FDA must keep a record of the correction or removal.

The information collected in the reports of corrections and removals will be used by FDA to identify marketed devices that have serious problems and

to ensure that defective devices are removed from the market. This will assure that FDA has current and complete information regarding these corrections and removals to determine whether recall action is adequate. Failure to collect this information would prevent FDA from receiving timely information about devices that may have a serious effect on the health of users of the devices.

Reports of corrections and removals may be submitted to FDA via mail or using FDA's Electronic Submission Gateway (ESG). We estimate that approximately 99 percent of submitters will use the ESG. Our estimate of the

reporting and recordkeeping burden is based on Agency records and our experience with this program, as well as similar programs that utilize FDA's ESG.

For respondents who submit corrections and removals using the electronic process, the operating and maintenance costs associated with this information collection are approximately \$30 per year to purchase a digital verification certificate (certificate must be valid for 1 to 3 years). This burden may be minimized if the respondent has already purchased a verification certificate for other electronic submissions to FDA. However, FDA is assuming that all

respondents who submit corrections and removals using the electronic process will be establishing a new WebTrader account and purchasing a digital verification certificate. We therefore estimate the total operating and maintenance costs to be \$30,660 annually (1,022 respondents × \$30).

In the **Federal Register** of March 20, 2017 (82 FR 14367), 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>

Activity (21 CFR part)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours <sup>2</sup>	Total operating and maintenance costs
Electronic process setup <sup>3</sup> .....	1,022	1	1,022	3.08	3,148	\$30,660
Submission of corrections and removals (part 806) .....	1,033	1	1,033	10	10,330	.....

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

<sup>2</sup> Totals may not sum due to rounding.

<sup>3</sup> We estimate that approximately 99 percent of respondents will submit corrections and removals using the electronic process. The actual burden hours for setup of the electronic process listed in the reporting burden table are divided by 3 to avoid double counting in the Office of Information and Regulatory Affairs Consolidated Information System. However, the one-time Average Burden per Response is 9.25 hours, resulting in a total one-time burden of 9,454 hours for the setup of the electronic process.

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

Activity (21 CFR part)	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Records of corrections and removals (part 806) .....	93	1	93	10	930

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

Dated: June 20, 2017.

**Anna K. Abram,**  
Deputy Commissioner for Policy, Planning,  
Legislation, and Analysis.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2008-N-0312]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Extralabel Drug Use in Animals**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of

certain information by the Agency. Under the Paperwork Reduction Act of 1995 (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 the reporting requirements associated with extralabel drug use in animals.

**DATES:** Submit either electronic or written comments on the collection of information by August 25, 2017.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before August 25, 2017. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of August 25, 2017. Comments received by mail/hand

delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

*Electronic Submissions*

Submit electronic comments in the following way.

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that