

ANNUAL BURDEN ESTIMATES—NEW INSTRUMENT

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hour per response	Total annual burden hours ¹
Participant 30-month survey	11,840	3,947	1	.5	1,974

ANNUAL BURDEN ESTIMATES—CHANGES TO ESTIMATED NUMBER OF RESPONDENTS

[Instruments previously approved]

Previously approved instrument	Updates to total number of respondents	Updates to annual number respondents	Number of responses per respondent	Average burden hour per response	Updated annual burden hours ¹
Participant Contact Information Form (5 STED sites).	2800 additional respondents.	933	1	.08	75
Participant Baseline Information Form (5 STED sites).	2800 additional respondents.	933	1	.17	159
Participant STED tracking letters	2178 additional respondents.	726	5	.05	182
Participant 6-month survey (Adult sites)	960 additional respondents.	320	1	.5	160
Participant 6-month survey (Young Adult sites) ...	960 fewer respondents	- 320	1	.5	- 160
Participant 12-month survey (Adult sites)	1440 additional respondents.	480	1	.75	360
Participant 12-month survey (Young Adult sites)	800 additional respondents.	267	1	.75	200

Increase in Est. Annual Burden Hours for Previously Approved ICs: 976.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families and the Employment and Training Administration are 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, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. Email address: 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 agencies, including whether the information shall have practical utility; (b) the accuracy of the agencies' 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.

Karl Koerper,
Reports Clearance Officer.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Request for Specific Consent to Juvenile Court Jurisdiction.

OMB No.: 0970-0385.

Description: The William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008 (TVPRA of 2008), Public Law 110-457 was enacted into law December 23, 2008. Section 235(d) directs the Secretary of HHS to grant or deny requests for specific consent for unaccompanied alien children in HHS custody who seek to invoke the jurisdiction of a state court for a dependency order and who also seek to invoke the jurisdiction of a state court to determine or alter his or her

custody status or release from ORR. These requests can be extremely time sensitive since a child must ask a state court for dependency before turning 18 years old.

In developing procedures for collecting the necessary information from unaccompanied alien children, their attorneys, or other representatives to allow HHS to approve or deny consent requests, ORR/DUCS devised a form. Specifically, the form asks the requestor for his/her identifying information, basic identifying information on the unaccompanied alien child, the name of the HHS-funded facility where the child is in HHS custody and care, the name of the court and its location, and the kind of request (e.g., for a change in custody, etc.). The form also asks that the unaccompanied alien child's attorney or authorized representative attach a Notice of Representation, which is an approved federal government agency form used for immigration procedures that authorizes the attorney to act on behalf of the child (i.e., G-28, EOIR-28, EOIR-29), or any other form of authorization to act on behalf of the unaccompanied alien child.

Respondents: Attorneys, accredited legal representatives, or others authorized to act on behalf of a unaccompanied alien child.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Request for Specific Consent	30	1	0.33	9.9

Estimated Total Annual Burden Hours: 9.9

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.

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, Fax: 202-395-7285, Email: OIRA_SUBMISSION@OMB.EOP.GOV.

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

Robert Sargis,
Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0723]

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

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 April 28, 2014.

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 oira_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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 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.

Reports of Corrections and Removals of Medical Devices and Radiation Emitting Products—(OMB Control Number 0910-0359)—Extension

I. Reports of Corrections and Removals

Under § 806.10 (21 CFR 806.10), each device manufacturer or importer shall submit a written report to FDA of any action initiated to correct or remove a device to reduce a risk to health posed by the device or to remedy a violation of the Federal Food, Drug, and Cosmetic Act caused by the device, which may present a risk to health within 10 working days of initiating the correction or removal.

Under § 806.20(a) (21 CFR 806.20(a)), each device manufacturer or importer of a device who initiates a correction or removal of a device that is not required to be reported to FDA shall keep a record of the correction or removal.

FDA currently accepts by mail reports of corrections and removals (806 reports) associated with medical and radiation emitting products regulated by the Center for Devices and Radiological Health (CDRH) under part 806.

For general information and assistance with 806 reports, contact the

CDRH Division of Small Manufacturers, International and Consumer Assistance (DSMICA) by telephone: 1-800-638-2041 or 301-796-7100, or by email: dsmica@fda.hhs.gov.

II. Proposed Electronic Submission Process

FDA is now proposing to make available, as a voluntary alternative to paper submissions, an electronic process for submitting 806 reports. The electronic process is expected to enhance consistency of submission data and to speed submission processing. Submission by mail will remain available and will be augmented by the new electronic submission process.

Establishing a process for using electronic submissions does necessitate some preparation by reporters, which includes obtaining both: (1) A WebTrader account and (2) a digital verification certificate. Many other FDA applications also utilize WebTrader. If an applicant already has an account with the WebTrader Electronic Submission Gateway (ESG) and a digital verification certificate (certificate must be valid for 1 to 3 years), no additional burden or cost will be incurred outside of the time it takes to make the submission of corrections and removals. However, for calculating the burden for this collection, FDA is assuming that all respondents will be establishing a new WebTrader account and purchasing a digital verification certificate.

Establishing a new account for sending electronic submissions may take up to 2 weeks. During that time, new reporters are advised to submit paper reports to avoid inadvertently missing the 10-day timeframes associated with submission of reports under part 806.

Upon approval of the information collection, a submitter would go to <http://www.fda.gov/ForIndustry/FDAeSubmitter/default.htm> to submit an 806 report via the electronic portal. Additional information about FDA's ESG is posted online at <http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm>. You can also email