(SRAE) Program—National Descriptive Study

OMB NO.: [NEW]

Description: The Administration for Children and Families (ACF) proposes a data collection effort related to the National Evaluation of the Sexual Risk Avoidance Education (SRAE) Program—National Descriptive Study.

The National Descriptive Study (of the National Evaluation of the SRAE Program) has multiple components. This information collection request only pertains to the Early Implementation Study, which will provide an early catalogue of SRAE programs' implementation. ACF seeks approval to collect the following information:

—Survey for Use with SRAE grantees. *The purpose of this collection effort is to conduct surveys with administrators/program directors in each of the states/organizations that received SRAE grants to better understand what key decisions states/organizations made regarding the design of their SRAE-funded programs and why they made those decisions.*

Interview Guide for Use with SRAE grantees. *The purpose of this collection effort is to conduct semi-structured interviews, that follow-on the surveys, with administrators/program directors in each of the states/organizations that received SRAE grants: The interviews will offer long-answer, qualitative responses to key questions, to better understand what key decisions states/organizations made regarding the* design of their SRAE-funded programs and why they made those decisions.

Respondents: State level administrators; Agency administrators; Organization heads; Project directors

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
Survey for SRAE Grantees	125	1	1	1	125
Interview Guide for SRAE Grantees	125	1	1	1	125

Estimated Total Annual Burden Hours: 250 hours.

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.* 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.

Emily Jabbour,

ACF/OPRE Certifying Officer.

[FR Doc. 2018–24997 Filed 11–15–18; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: National Youth in Transition Database (NYTD) and Youth Outcomes Survey.

OMB No.: 0970–0340.

Description: The Foster Care Independence Act of 1999 (42 U.S.C. 1305 *et seq.*) as amended by Public Law 106–169 requires State child welfare agencies to collect and report to the Administration on Children and Families (ACF) data on the characteristics of youth receiving independent living services and information regarding their outcomes. The regulation implementing the National Youth in Transition Database, listed in 45 CFR 1356.80, contains standard data collection and reporting requirements for States to meet the law's requirements. Additionally, the Family First Prevention Services Act of 2017 (H.R. 253) further outlines the expectation of the collection and reporting of data and outcomes regarding youth who are in receipt of independent living services. ACF will use the information collected under the regulation to track independent living services, assess the collective outcomes of youth, and potentially to evaluate State performance with regard to those outcomes consistent with the law's mandate.

Respondents: State agencies that administer the John H. Chafee Foster Care Independence Program. The U.S. Virgin Islands have been included in this request as they are expected to begin participating in NYTD data collection efforts during this approval period.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Data file	53	2	1,430	151,580
Youth Outcomes Survey	16,333	1	.50	8,167

Estimated Total Annual Burden Hours: 155,529.

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, 330 C Street SW, Washington, DC 20201. Attention 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 Email: *OIRA_SUBMISSION@OMB.EOP.GOV. Attn:* Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2018–25053 Filed 11–15–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2017–M–6970, FDA–2017–M–6971, FDA–2017–M–6983, FDA–2017–M–6984, FDA–2017–M–7004, FDA–2018–M–0411, FDA–2018–M–0528, FDA–2018–M–0620, FDA–2018–M–0736, FDA–2018–M–0737, FDA–2018–M–00–0738, FDA–2018–M–0792, FDA–2018–M–1371, FDA–2018–M–1215, FDA–2018–M–1237, FDA–2018–M–1372, FDA–2018–M–1446, FDA–2018–M–1447, FDA–2018–M–1580, FDA–2018–M–1581, FDA–2018–M–1634, FDA–2018–M–1727, FDA–2018–M–1791, FDA–2018–M–1753, FDA–2018–M–1970, FDA–2018–M–2118, FDA–2018–M–2119, FDA–2018–M–2237, FDA–2018–M–2269, FDA–2018–M–2335, FDA–2018–M–2460, FDA–2018–M–2461, FDA–2018–M–2462, FDA–2018–M–2463, FDA–2018–M–2571, FDA–2018–M–2883, FDA–2018–M–2884, FDA–2018–M–2885, FDA–2018–M–2886, FDA–2018–M–2887, FDA–2018–M–2983, FDA–2018–M–3131, FDA–2018–M–3153, FDA–2018–M–3212, FDA–2018–M–3503, FDA–2018–M–3505, and FDA–2018–M–3548]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) and humanitarian device exemption applications (HDEs), that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the internet and the Agency's Dockets Management Staff.

ADDRESSES: You may submit comments as follows:

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 identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket Nos. FDA–2017–M–6970, FDA–2017–M–6971, FDA–2017–M–6983, FDA–2017–M–6984, FDA–2017–M–7004, FDA–2018–M–0411, FDA–2018–M–0528, FDA–2018–M–0620, FDA–2018–M–0736, FDA–2018–M–0737, FDA–2018–M–00–0738, FDA–2018–M–0792, FDA–2018–M–1371, FDA–2018–M–1215, FDA–2018–M–1237, FDA–2018–M–1372, FDA–2018–M–1446, FDA–2018–M–1447, FDA–2018–M–1580, FDA–2018–M–1581, FDA–2018–M–1634, FDA–2018–M–1727, FDA–2018–M–1791, FDA–2018–M–1753, FDA–2018–M–1970, FDA–2018–M–2118, FDA–2018–M–2119, FDA–2018–M–2237, FDA–2018–M–2269, FDA–2018–M–2335, FDA–2018–M–2460, FDA–2018–M–2461, FDA–2018–M–2462, FDA–2018–M–2463, FDA–2018–M–2571, FDA–2018–M–2883, FDA–2018–M–2884, FDA–2018–M–2885, FDA–2018–M–2886, FDA–2018–M–2887, FDA–2018–M–2983, FDA–2018–M–3131, FDA–2018–M–3153, FDA–2018–M–3212, FDA–2018–M–3503, FDA–2018–M–3505, and FDA–2018–M–3548 for ''Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf* .