information form, which will collect demographic data and information on the respondent's work and education history.

Follow-Up Surveys. Follow-up telephone surveys will be conducted with all participants. There will be three follow-up surveys in each of the STED and ETJD sites (including the two sites that are also part of ETJD), approximately 6, 12, and 30 months after study entry.

Implementation Research and Site Visits. Data on the context for the programs and their implementation is collected during two rounds of site visits to each of the twelve sites, including interviews, focus groups, observations, and case file reviews. These data will be supplemented by short questionnaires for program staff, clients, worksite supervisors, and participating employers, as well as a time study for program staff.

This notice is specific to the request for approval of the 30-month survey, which will measure the differences in employment, wage progression, income, and other outcomes between the program groups and similar group of respondents who were randomly assigned to a control group. The information collection request will also include increased burden hours to include additional respondents. This increase is a result of the actual enrollment numbers at recruited sites.

Respondents: Study participants in the treatment and control groups.

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.

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: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *OPREinfocollection@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.

Karl Koerper,

Reports Clearance Officer.

[FR Doc. 2014–12552 Filed 5–29–14; 8:45 am]

BILLING CODE 4184–09–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: DRA TANF Final Rule.

OMB No.: 0970–0338.

Description: When the Deficit Reduction Act of 2005 (DRA) reauthorized the Temporary Assistance for Needy Families (TANF) program, it imposed a new data requirement that States prepare and submit data verification procedures and replaced other data requirements with new versions including: the TANF Data Report, the SSP–MOE Data Report, the Caseload Reduction Documentation Process, and the Reasonable Cause/Corrective Compliance Documentation Process. The Department of Health and Human Services Appropriations Act, P.L. 113–76 extended the TANF program through September 2014. We are proposing to continue these information collections without change.

Respondents: States, Territories and Tribes.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Preparation and Submission of Data Verification Procedures §§ 261.60–261.63	54	1	640	34,560
Caseload Reduction Documentation Process, ACF–202 §§ 261.41 & 261.44	54	1	120	6,480
Reasonable Cause/Corrective Compliance Documentation Process §§ 262.4, 262.6, & 262.7; § 261.51	54	2	240	25,920
TANF Data Report Part 265	54	4	2,201	475,416
SSP–MOE Data Report Part 265	29	4	714	82,824
Estimated Total Annual Burden Hours				625,200

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, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2014–12498 Filed 5–29–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0575]

Guidance for Industry on Expedited Programs for Serious Conditions—Drugs and Biologics; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Expedited Programs for Serious Conditions—Drugs and Biologics.'' The purpose of this guidance is to provide a single resource for information on FDA's policies and procedures related to expedited drug development and review programs. The following programs are intended to facilitate and expedite development and review of new drugs to address unmet medical need in the treatment of a serious or life-threatening condition (expedited programs): Fast track designation, breakthrough therapy designation, accelerated approval, and priority review designation. This guidance finalizes the draft guidance issued in June 2013.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Melissa Robb, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6360, Silver Spring, MD 20993–0002, 301–796–2500; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Expedited Programs for Serious Conditions—Drugs and Biologics.'' This guidance provides a single resource for information on FDA's policies and procedures related to the following expedited programs for serious conditions: (1) Fast track designation, (2) breakthrough therapy designation, (3) accelerated approval, and (4) priority review designation. The guidance describes threshold criteria generally applicable to expedited programs, including what is meant by serious condition, unmet medical need, and available therapy. This guidance also discusses considerations for expedited development and review such as manufacturing and product quality, nonclinical studies, and clinical inspections. In addition, this guidance aligns CDER's criteria for priority review designation with CBER's criteria. Only products intended to treat a serious condition are eligible for priority review (unless otherwise eligible under specific statutory provisions).

For over 30 years, expediting the availability of promising therapies to patients with serious conditions has been a priority for FDA. With the passage of the Food and Drug Administration Safety and Innovation Act (FDASIA) (Public Law 112–122), FDA is expanding its efforts to expedite development and review of therapies intended to treat patients with serious conditions. This guidance is intended to satisfy the statutory requirements of sections 901(c)(2) and 902(b)(1)(A) of FDASIA.

Section 901(c)(2) of FDASIA requires FDA to issue a final guidance document to implement amendments to the Federal Food, Drug, and Cosmetic Act (the FD&C Act) made by section 901 of