these barriers through the conduct of a randomized, controlled intervention trial of a Web site-based lifestyle program, Balance after Baby (BAB), that is adapted from the DPP and tailored specifically for postpartum women with recent GDM.

The project aims to screen 293 (98 annualized over 3 years) women with a recent GDM pregnancy for enrollment into the study, followed by assessments at the following five post-partum time points: 6-Weeks, 6-months, 12-months, 18-months, and 24-months. Of the estimated 190 (63 annualized) women who are anticipated to meet eligibility requirements and attend the first study visit, approximately half will be assigned to the control group and the other half will be assigned to the intervention group. Women in the control group will have access to a ''control version'' of the BABI Web site, containing post-partum information such as the ''It's Never too Early to Prevent Diabetes'' tip sheet and links to other related public Web sites. Those assigned to the intervention group will have access to the full, interactive version of the BABI Web site and will be instructed to log-on once a week to view educational modules regarding healthy lifestyle options and to enter and track their weight and physical activity against their self-appointed goals. They will also have access to a web-based Lifestyle Coach who will communicate with them throughout the first year of their participation.

All participants will be required to complete clinical assessment visits involving the completion of visit-specific questionnaires with integrated food frequency questionnaires, laboratory testing, and the collection of physical measurements such as height and weight. The results of the two study arms, intervention and control, will be compared to assess whether the intervention significantly increased postpartum weight loss and decreased glucose tolerance for women at increased T2DM risk.

For the calculation of the estimated burden hours per study visit detailed in the table below, a constant 5% rate of exclusion and attrition was applied between visits. The burden table provides a participant estimate, which will be evenly distributed across control and intervention groups for each information collection step (both groups complete the same questionnaires), annualized over a 3-year clearance period. Therefore, of the 190 women (63 annualized) who attend the 6-week visit, the estimated number of participants returning for the 6-month visit is reduced to 180 (60 annualized), followed by 172 (57 annualized), 162 (54 annualized), and 154 (51 annualized) for the 12-, 18-, and 24-month visits respectively. The average burden per questionnaire ranges from 8 minutes for the BABI Screener Questionnaire up to 18 minutes for the BABI 6-Month Questionnaire. The average burden hours per response for the 6-Week, 6-, 12-, 18-, 24-Month Questionnaires, and Block© Food Frequency Questionnaire (FFQ) are shown in the table below. Participation is voluntary and there are no costs to respondents other than their time.

The total estimated annualized burden hours are 183.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	No. of respondents	No. of responses per respondent	Avg. burden per response (in hrs.)
Women with a recent history GDM	BABI Screener Questionnaire	98	1	8/60
	BABI 6-Week Questionnaire	63	1	17/60
	BABI 6-Month Questionnaire	60	1	18/60
	BABI 12-Month Questionnaire	57	1	14/60
	BABI 18-Month Questionnaire	54	1	14/60
	BABI 24-Month Questionnaire	51	1	15/60
	Block FFQ	63	5	18/60

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2016–01099 Filed 1–20–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration For Children And Families

[CFDA Number: 93.508]

Announcing the Award of Six Single-Source Program Expansion Supplement Grants From the Tribal Maternal, Infant, and Early Childhood Home Visiting (Tribal MIECHV) Program

AGENCY: Office of Child Care, Administration for Children and Families, HHS.

ACTION: Notice of the award of six single-source program expansion supplement grants to grantees of the Tribal Maternal, Infant, and Early Childhood Home Visiting (Tribal MIECHV) Program.

SUMMARY: The Administration for Children and Families (ACF), Office of Child Care (OCC), Tribal Maternal, Infant, and Early Childhood Home Visiting (Tribal MIECHV) Program, announces the award of single-source program expansion supplement grants to the Confederated Salish and Kootenai Tribes in Pablo, MT; Confederated Tribes of Siletz Indians in Siletz, OR; Inter-Tribal Council of Michigan in Sault Ste. Marie, MI; Red Cliff Band of Lake Superior Chippewa in Bayfield, WI; the Choctaw Nation of Oklahoma in Durant, OK; and the Cherokee Nation of Oklahoma in Tahlequah, OK.

The Fiscal Year 2015 single-source program expansion supplement grants will support the expansion of the Tribal Early Learning Initiative (TELI) program.

DATES: The period of support is September 30, 2015—September 29, 2016.

FOR FURTHER INFORMATION CONTACT: Rachel Schumacher, Director, Office of Child Care, 901 D Street, SW., Washington, DC 20024. Telephone: (202) 401–6984; Email: *rachel.schumacher@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION: In response to the success of the TELI pilot, the Office of Child Care has awarded single-source program expansion supplement awards to six Tribal MIECHV grantees for expansion of the TELI program.

Objectives of the TELI Expansion

1. Identify and analyze systems issues, including obstacles that could block efforts to build and maintain partnerships, fully and effectively coordinate tribal early childhood development programs, and develop a menu of alternative interventions and strategies in line with tribal community values, traditions, and priorities.

2. Develop tribally driven goals and concrete objectives in each local tribal community for building effective and efficient early childhood systems, high-quality programs, and improved outcomes for young children and families.

3. Develop and carry out concrete community plans for supporting and strengthening cooperation, coordination, resource sharing and leveraging, and integration among programs that support young children and families in the tribal community.

4. Share plans of action, barriers and challenges, opportunities and solutions, and the results of action plans with other tribal communities in an effort to further develop peer-learning relationships.

Applications received from the grantees underwent objective review using criteria such as the applicants' ability to clearly describe the early learning and development programs that will participate in the TELI; their ability to describe existing challenges and strengths to collaboration across their participating early learning and development programs; and whether the submitted budget and budget justification narrative provided for reasonable project costs.

The Following Awards Are Made

A single-source program expansion supplemental grant of $96,000 to the Confederated Salish and Kootenai Tribes in Pablo, MT, to support the development of a shared data system for its early childhood programs that include Head Start, Child Care, and Home Visiting that will allow programs to improve client services by increasing accessibility and reducing wait time and travel time between agencies; a more efficient client information system; promotion of long-term, cross-agency communication and collaboration; improved management systems; and expansion of deliverables such as service reports, outcome analysis, evaluation, assessment success, and other data-driven tools that in turn help to demonstrate the program's viability and value to community funding agencies.

A single-source program expansion supplemental grant of $96,000 to the Confederated Tribes of Siletz Indians in Siletz, OR, to support the identification and analysis of systems issues, including the identification of obstacles that could block efforts to build and maintain partnerships; coordination of Siletz tribal early childhood development programs, and the development of a menu of alternative interventions and strategies, that honor tribal community values, traditions, and priorities; and the development of tribally driven goals and concrete objectives in each local tribal community that support building effective early childhood systems and the development of specific community plans that support and strengthen cooperation, coordination, resource-sharing and leveraging, and the integration of programs in the Siletz Service Area.

A single-source program expansion supplemental grant of $120,000 to the Inter-Tribal Council of Michigan in Sault Ste. Marie, MI, to improve and increase the positive impact of services on families throughout the state through an early childhood system that will provide support and services across the full range of needs from the prenatal period through kindergarten entry; reflect and build on the strengths and wisdom of tribal community values and culture; maximize the use of resources to foster efficiency, yielding maximum impact for each investment; and ensure sustainability, consistency, and ease-of-access at the community level through referral and transition processes that will effectively engage parents as key stakeholders.

A single-source program expansion supplemental grant of $96,000 to the Red Cliff Band of Lake Superior Chippewa in Bayfield, WI, to support the identification and analysis of systems issues to develop a menu of alternative interventions and strategies that honor tribal community values, traditions, and priorities; development of tribally driven goals and concrete objectives in each local tribal community to build effective and efficient early childhood systems, high-quality programs, and improved outcomes for children and families; identification of service providers that support families with young children; provision of training that will deepen the understanding of Trauma-Informed Care and education on the identification and support for individuals experiencing a mental health crisis; and the development of a 5-year plan that identifies data needs for collection, storage, and data protection to improve the coordination and sharing of key child and family data.

A single-source program expansion supplemental grant of $96,000 to the Choctaw Nation of Oklahoma in Durant, OK, for its coordinated effort between the following Choctaw Nation programs: Chahta Inchukka, Chahta Vlla Apela, Child Care Assistance (Child Care Development Fund), Head Start, Early Head Start (Early Head Start-Child Care Partnership), and the Child Development Day Care Program. Through this initiative, program directors will coordinate their programs to create and support a seamless, high-quality, early-childhood system; raise the quality of services to children and families across the pregnancy-to-kindergarten-entry continuum; and identify and break down barriers to collaboration and systems improvement. The Choctaw Nation will commit a TELI coordinator to work across all of Choctaw's early childhood TELI programs; host a shared training for all early learning program staff that will provide professional development on a relevant early childhood topic and offer the opportunity for staff to learn about other programs and network; and complete research about potential data systems that will better coordinate the sharing of relevant child and family data across programs.

A single-source program expansion supplemental grant of $96,000 to the Cherokee Nation of Oklahoma in Tahlequah, OK, to support collaboration between Cherokee PARENTS, Head Start, Early Head Start, and Child Care, and develop a holist approach to child development. The Cherokee Nation plans to develop a strategic work team comprised of a diverse group of stakeholders; share professional development between each program, including conferences and trainings; hold monthly parent/cultural/community meetings; develop a unified assessment tool for assessing the needs of children and families; build a unified resource guide; give priority in referrals

between programs by identifying gaps, weaknesses, and shortfalls in program design; and focusing on shared resources to reduce duplicative and burdensome processes.

Statutory Authority: Section 511 of the Title V of the Social Security Act, as added by Section 2951 of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148), and amended by the Protecting Access to Medicare Act of 2014 (Pub. L. 113–93) and the Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10).

Mary M. Wayland,

Senior Grants Policy Specialist, Division of Grants Policy, Office of Administration.

[FR Doc. 2016–01033 Filed 1–20–16; 8:45 am]

BILLING CODE 4184–43–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–0839]

Target Animal Safety Data Presentation and Statistical Analysis; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry (GFI) #226 entitled ''Target Animal Safety Data Presentation and Statistical Analysis.'' The purpose of this document is to provide recommendations to industry regarding the presentation and statistical analyses of target animal safety (TAS) data submitted to the Center for Veterinary Medicine (CVM) as part of a study report to support approval of a new animal drug. These recommendations apply to TAS data generated from both TAS and field effectiveness studies conducted in companion animals (*e.g.,* dogs, cats, and horses) and food animals (*e.g.,* swine, ruminants, fish, and poultry).

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

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

• Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, 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 No. FDA–2015–D–0839 for Target Animal Safety Data Presentation and Statistical Analysis. Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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 *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. 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.

FOR FURTHER INFORMATION CONTACT: Virginia Recta, Center for Veterinary Medicine (HFV–160), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0840, *virginia.recta@fda.hhs.gov,*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 31, 2015 (80 FR 17047), FDA published the notice of availability for a draft guidance entitled ''Target Animal Safety Data Presentation and Statistical Analysis'' giving interested persons until June 1, 2015, to comment on the draft guidance. FDA received two comments on the draft guidance and those comments were considered as the guidance was finalized. Some of the suggested changes were incorporated, and additional editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated March 2015.

This GFI provides recommendations to industry regarding the presentation