annualized burden of 607 hours per year.

There are no costs to participants other than the time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Private companies	EXCEL data template	28	260	5/60

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. 2014–27350 Filed 11–18–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA Numbers: 93.592]

Announcing the Award of a Single-Source Program Expansion Supplement Grant to the National Resource Center on Domestic Violence (NRCDV) in Harrisburg, PA

AGENCY: Family and Youth Services Bureau, ACYF, ACF, HHS.

ACTION: Notice of the award of a single-source program expansion supplement grant under the Family Violence Prevention and Services Act (FVPSA) Technical Assistance (TA) Project to the National Resource Center on Domestic Violence to support training and technical assistance activities.

SUMMARY: The Administration for Children and Families (ACF), Administration on Children, Youth and Families (ACYF), Family and Youth Services Bureau (FYSB), Division of Family Violence and Prevention Services (DFVPS) announces the award of $236,000 as a single-source program expansion supplement to the National Resource Center on Domestic Violence in Harrisburg, PA. The grantee, funded under the Family Violence Protection and Services Act (FVPSA) program, is a technical assistance (TA) provider that assists FVPSA service providers to build the capacity of domestic violence programs.

DATES: The period of support for the single-source program expansion supplement is September 30, 2014 through September 29, 2015.

FOR FURTHER INFORMATION CONTACT: Shawndell Dawson, Senior Program Specialist, Family Violence Prevention and Services Program, 1250 Maryland Avenue SW., Suite 8219, Washington, DC 20024. Telephone: 202–205–1476; Email: *Shawndell.Dawson@acf.hhs.gov*.

SUPPLEMENTARY INFORMATION: Supplemental award funds will support the grantee in providing training and technical assistance to domestic violence service providers. A portion of the supplemental award is contributed by the Centers for Disease Control (CDC) and Prevention's National Center for Injury Prevention and Control (NCIPC), Division of Violence Prevention (DVP).

This award will expand the scope of the NRCDV's technical assistance activities to include additional activities concerning the prevention of intimate partner violence (IPV) by: (1) Coordinating engagement with national-level partners, including foundations, for the purpose of enhancing communication related to IPV prevention; 2) engaging in planning to facilitate dialogue that will include the sharing of tools and lessons learned among state domestic violence coalitions engaged in IPV primary prevention efforts; 3) continuing to identify and disseminate information on lessons learned and key findings from state domestic violence coalitions that have implemented IPV primary prevention activities through *www.PreventIPV*org, and other means; 4) maintaining a virtual workspace to assist in the sharing of resources among state and territorial domestic violence coalitions that are engaged in IPV primary prevention activities; and 5) facilitating regular, ongoing communication between the IPV Prevention Council, ACF/DFVPS, and CDC/DVP.

In addition to the prevention activities, the grantee will coordinate an accessibility and sustainability peer-to-peer technical assistance collaborative with three to five state domestic violence coalitions, which may involve activities such as: (1) Identifying state coalitions with experience in addressing organizational accessibility challenges (i.e. mental health, substance use, men, and adolescent boys), or sustainability challenges (i.e. fiscal management or board management); (2) coordinating support to domestic violence organizations or coalitions experiencing accessibility or sustainability challenges; and (3) developing peer-informed accessibility and sustainability tools and resources, and a discussion forum, for use by all domestic violence coalitions.

Statutory Authority: Section 310 of the Family Violence Prevention and Services Act, as amended by Section 201 of the CAPTA Reauthorization Act of 2010, Pub. L. 111–320. The statutory authority for the additional funds from the Centers for Disease Control and Prevention is 42 U.S.C. 247b(k)(2) and 42 USC 280b–1 of the Public Health Service Act.

Christopher Beach,

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

[FR Doc. 2014–27390 Filed 11–18–14; 8:45 am]

BILLING CODE 4184–32–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1855]

Agency Information Collection Activities; Proposed Collection; Comment Request: Experimental Studies on Consumer Perceptions of Modified Risk Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on Experimental Studies on Consumer Perceptions of Modified Risk Tobacco Products (MRTPs).

DATES: Submit either electronic or written comments on the collection of information by January 20, 2015.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the 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, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Experimental Studies on Consumer Perceptions of Modified Risk Tobacco Products—(OMB Control Number 0910–NEW)

FDA's Center for Tobacco Products proposes to conduct experimental studies to develop generalizable scientific knowledge to help inform its implementation of section 911 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 387k), wherein FDA will be evaluating information submitted to the Agency about how consumers understand and perceive tobacco products marketed as MRTPs. Section 911 of the FD&C Act authorizes FDA to grant orders to persons to allow the marketing of MRTPs. The term ''modified risk tobacco product'' means any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products. FDA must issue an order authorizing the marketing of an MRTP if the Agency determines that the product, as it is actually used by consumers, will significantly reduce harm and the risk of tobacco-related disease to individual tobacco users and benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products (section 911(g)(1) of the FD&C Act).

FDA may also issue an order authorizing the marketing of an MRTP that reduces or eliminates exposure to a harmful substance if, among other requirements, the Agency determines that the order would be appropriate to promote the public health, the issuance of the order is expected to benefit the population as a whole taking into account both users and nonusers of tobacco products, and the existing evidence demonstrates that a measurable and substantial reduction in morbidity and mortality among individual tobacco users is reasonably likely to be shown in subsequent studies (section 911(g)(2) of the FD&C Act). In addition, section 911 requires that any advertising or labeling concerning modified risk products enable the public to comprehend the information concerning modified risk and to understand the relative significance of such information in the context of total health and in relation to all of the diseases and health related conditions associated with the use of tobacco products (section 911(h)(1) of the FD&C Act). The proposed research will inform the Agency's efforts to implement the provisions of the FD&C Act related to MRTPs.

FDA proposes to conduct experimental studies in order to develop generalizable scientific information to better understand how consumers perceive and understand these products, how exposure to claims about modified risk or exposure influence intentions to try or purchase the product (i.e., product adoption), and how individual characteristics such as current tobacco use and/or brand loyalty might influence these outcomes. Moreover, information from the experimental studies may assist FDA to determine the appropriate methods and measures for gathering such information from consumers.

The impact of different claims pertaining to modified risk or exposure on understanding, perceptions, and potential product adoption (i.e., intention to try) will be evaluated by conducting a series of three studies that, in turn, will examine: The impact of claims about cigarette (Study 1) or smokeless tobacco products (Study 2) among young adult and adult current, former, or never users of tobacco; and the impact of claims on adolescents currently using, or susceptible to using, tobacco (Study 3). All three studies will assess individual-level factors that might influence the impact of claims on consumer responses, including: Brand loyalty, tobacco use history and behavior, concerns about health risks, and openness to new products.

Across all studies, participants will be randomized to either see modified risk claims or not (control condition). In Studies 1 and 2, modified risk claims will be displayed on mock tobacco product packages and ads. For ethical reasons, adolescents (Study 3) will see modified risk claims displayed as statements alone, not attached to product packaging or ads. Consumer reactions to claims will be evaluated by measuring constructs such as: Comprehension of the modified risk information in the claims, perceived benefits of the product, perceptions of harm and risk, misbeliefs about the product, quit intentions, and willingness to try or purchase the product.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Adult Screener	24,000	1	24,000	0.03 (2 minutes)	720
Study 1 (Adults)	1,800	1	1,800	0.333 (20 minutes)	599
Study 2 (Adults)	600	1	600	0.333 (20 minutes)	200
Total adult hours					1,519
Youth Screener	6,000	1	6,000	0.03 (2 minutes)	180
Study 3 (Youth)	600	1	600	0.333 (20 minutes)	200
Total youth hours					380
Total Hours					1,899

FDA's burden estimate is based on prior experience with research that is similar to this proposed study. Approximately 30,000 respondents will complete a screener to determine eligibility for participation in a study, estimated to take approximately 2 minutes (0.03 hours), for a total of 900 hours for screening activities. Three thousand respondents will complete a full study, estimated to last 20 minutes (0.333 hours), for a total of 999 hours for completion of both adult studies and one youth study. The estimated total hour burden of the collection of information is 1,899 hours.

Dated: November 12, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–27283 Filed 11–18–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1840]

Electronic Study Data Submission; Data Standards; Validation Rules for Study Data Tabulation Model Formatted Studies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) is announcing the availability of a document entitled ''Validation Rules for Study Data Tabulation Model (SDTM) Formatted Studies.'' CDER is making this document available to improve the standardization and quality of clinical data submitted to CDER, as well as to improve the predictability of data quality and usefulness.

FOR FURTHER INFORMATION CONTACT: Office of Strategic Programs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1192, Silver Spring, MD 20993, email: *edata@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: CDER supports the regulatory submission of standardized clinical study data based on the Clinical Data Interchange Standards Consortium SDTM. Upon receipt of the data, CDER validates the data using a set of validation rules. The ''Validation Rules for SDTM Formatted Studies'' is an Excel file that provides a human readable description of a rule set for validation. Submitters of clinical study data can use this information to understand how FDA validates the data. The file is available on FDA's Study Data Standards Resources Web page at *http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm.* It contains a combination of conformance rules (i.e., how well the data conform to the standard) and business rules (i.e., quality checks; how well the data may support useful analysis). The rules may be updated periodically as new or updated validation rules are developed. The Change History tab will provide a descriptive change history of the document.

Dated: November 14, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–27384 Filed 11–18–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–1120]

Vaginal Microbicides: Development for the Prevention of Human Immunodeficiency Virus Infection; Guidance for Industry; 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 ''Vaginal Microbicides: Development for the Prevention of HIV Infection.'' The purpose of this guidance is to assist sponsors in all phases of development of vaginal microbicides, defined as vaginal drug products that prevent human immunodeficiency virus (HIV) acquisition. The guidance outlines the types of nonclinical studies and clinical trials recommended throughout the drug development process to support approval of vaginal microbicides. This guidance finalizes the draft guidance issued on November 23, 2012.

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, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, 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.*