Dated: May 10, 2019.

Sandra Cashman,

Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2019–09998 Filed 5–14–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HELATH AND HUMAN SERVICES

Administration for Community Living

Intent To Award a Single-Source Supplement to the National Aging Network

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living is announcing its intent to Award a Single-Source Supplement to provide the National Aging Network with timely, relevant, high quality opportunities to further enhance their knowledge and skills related to nutrition services.

FOR FURTHER INFORMATION CONTACT: For further information or comments regarding this program supplement, contact Keri Lipperini, U.S. Department of Health and Human Services, Administration for Community Living, Administration on Aging, Office of Nutrition and Health Promotion Programs, 202–795–7422, email *keri.lipperini@acl.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Administration for Community Living (ACL) announces the intent to award a single-source supplement to the current cooperative agreement held by Meals on Wheels America for the project *Enhancing the Knowledge and Skills of the Aging Network.* The purpose of this supplement is to: (1) Support the development and dissemination of resources for experienced and inexperienced Aging Network Nutrition Program providers; and (2) enhance peer-learning opportunities for State Units on Aging (SUAs), Area Agencies on Aging (AAAs), and Nutrition Program providers.

The administrative supplement for FY 2019 will be in the amount of $257,401, bringing the total award for FY 2019 to $482,390.

The additional funding will not be used to begin new projects, but it will be used to enhance existing efforts. The grantee will continue to provide appropriate, quality nutrition-related resources, address new opportunities to embed nutrition services within the home and community-based service systems, and engage successfully in emerging models of integrated health care.

Program Name: Enhancing the Knowledge and Skills of the Aging Network.

Recipient: Meals on Wheels America.

Period of Performance: The supplement award will be issued for the second year of a three year project period of Sept 1, 2017 to August 31, 2020.

Total Award Amount: $482,390 in FY 2019.

Award Type: Cooperative Agreement Supplement.

Statutory Authority: The Older Americans Act (OAA) of 1965, as amended, Public Law 114–144.

Basis for Award

Meals on Wheels America (MOWA) is currently funded to carry out the objectives of this project through its current project entitled, *National Resource Center on Nutrition and Aging* for the period of September 1, 2017 through August 31, 2020. Since the project's implementation, the grantee has made satisfactory progress toward its approved work plan. The supplement will enable the grantee to carry their work even further, enhancing the support they provide to the Aging Network Nutrition Program Providers. The additional funding will not be used to begin new projects or activities, but rather to continue to enhance efforts specific to tribal populations and congregate meal settings.

MOWA is uniquely positioned to complete the work called for under this project. They have an already established infrastructure and are a known and trusted organization in the Aging Network. They have an established presence within much of the Aging Network. Under this current award period, they are providing educational opportunities for the Aging Network Nutrition Program Providers, including webinars and live trainings. They have a comprehensive, interactive web-based repository (*www.nutritionandaging.org*) with tools and resources, including—but not limited to—issues briefs, policy and practice models, and toolkits. They have also presented to the Aging Network locally and on a national level. They have reached thousands of providers using their: (1) Comprehensive database of SUAs, AAAs, and other Nutrition Program Providers; and (2) Leadership Academy, which provides expert consultation around nutrition program delivery and the use of technology to enhance services. In addition, they have developed partnerships with organizations, universities, and other entities to provide education and support for the Aging Network.

Establishing an entirely new grant project at this time would be potentially disruptive to the current work already well under way. More importantly, it could cause confusion among the Aging Network Nutrition Program Providers, which could have a negative effect on training and support opportunities. If this supplement were not provided, the project would be unable to address the significant unmet educational needs of the Aging Network Nutrition Program Providers.

Dated: May 9, 2019.

Mary Lazare,

Principal Deputy Administrator .

[FR Doc. 2019–10029 Filed 5–14–19; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0386]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments and Listing of Ingredients in Tobacco 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 (PRA).

DATES: Fax written comments on the collection of information by June 14, 2019.

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 0910–0650. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations,

Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments and Listing of Ingredients in Tobacco Products

OMB Control Number 0910–0650—Extension

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) was signed into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding, among other things, a chapter granting FDA important authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. The Tobacco Control Act created new requirements for the tobacco industry. Section 101 of the Tobacco Control Act amended the FD&C Act by adding sections 905 and 904 (21 U.S.C. 387e and 387d).

Section 905 of the FD&C Act requires the annual registration of any ''establishment in any State engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products.'' Section 905 requires this registration be completed by December 31 of each year. The Secretary of Health and Human Services (Secretary) has delegated to the Commissioner of Food and Drugs the responsibility for administering the FD&C Act, including section 905. Section 905 of the FD&C Act requires owners or operators of each establishment to register: (1) Their name; (2) places of business; (3) a list of all tobacco products that are manufactured by that person; (4) a copy of all labeling and a reference to the authority for the marketing of any tobacco product subject to a tobacco product standard under section 907 of the FD&C Act (21 U.S.C. 387g) or to premarket review under section 910 of the FD&C Act (21 U.S.C. 387j); (5) a copy of all consumer information and other labeling; (6) a representative sampling of advertisements; (7) upon request made by the Secretary for good cause, a copy of all advertisements for a particular tobacco product; and (8) upon request made by the Secretary, if the registrant has determined that a tobacco product contained in the product list is not subject to a tobacco product standard established under section 907 of the FD&C Act, a brief statement of the basis upon which the registrant made such determination.

FDA collects the information submitted pursuant to section 905 of the FD&C Act through an electronic portal, and through paper forms (Forms FDA 3741 and FDA 3741a) for those individuals who choose not to use the electronic portal.

FDA has also published a guidance for industry entitled ''Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments'' (*https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM191940.pdf*). This guidance is intended to assist persons making tobacco product establishment registration and product listing submissions to FDA.

Section 904(a)(1) of the FD&C Act requires that each tobacco product manufacturer or importer submit ''a listing of all ingredients, including tobacco, substances, compounds, and additives that are, as of such date, added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand and by quantity in each brand and subbrand'' by December 22, 2009. This section applies only to those tobacco products manufactured and distributed before June 22, 2009, and which are still manufactured as of the date of the ingredient listing submission.

Section 904(c) of the FD&C Act requires that a tobacco product manufacturer: (1) Provide all information required under section 904(a) of the FD&C Act to FDA ''at least 90 days prior to the delivery for introduction into interstate commerce of a tobacco product not on the market on the date of enactment'' of the Tobacco Control Act; (2) advise FDA in writing at least 90 days prior to adding any new tobacco additive or increasing in quantity an existing tobacco additive, except for those additives that have been designated by FDA through regulation as not a human or animal carcinogen, or otherwise harmful to health under intended conditions of use; and (3) advise FDA in writing at least 60 days prior to eliminating or decreasing an existing additive, or adding or increasing an additive that has been designated by FDA through regulation as not a human or animal carcinogen, or otherwise harmful to health under intended conditions of use.

FDA collects the information submitted pursuant to sections 904(a)(1) and (c) of the FD&C Act through an electronic portal, and through a paper form (Form FDA 3742) for those individuals who choose not to use the electronic portal.

In addition to the development of the electronic portal and paper form, FDA published a guidance entitled ''Listing of Ingredients in Tobacco Products.'' This guidance is intended to assist persons making tobacco product ingredient listing submissions. FDA also provides a technical guide, embedded hints, and a web tutorial to the electronic portal.

The Tobacco Control Act also gave FDA the authority to issue a regulation deeming all other products that meet the statutory definition of a tobacco product to be subject to chapter 9 of the FD&C Act (section 901(b) (21 U.S.C. 387a(b)). On May 10, 2016, FDA issued that rule, extending FDA's tobacco product authority to all products that meet the definition of tobacco product in the law (except for accessories of newly regulated tobacco products), including electronic nicotine delivery systems, cigars, hookah, pipe tobacco, nicotine gels, dissolvables that were not already subject to the FD&C Act, and other tobacco products that may be developed in the future (81 FR 28974 at 28976) (''the final deeming rule'').

In the **Federal Register** of October 23, 2018 (83 FR 53478), FDA published a 60-day notice requesting public comment on the proposed collection of information. Two comments were received; however, neither were PRA related.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA form/activity/FD&C act section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Tobacco Product Establishment Initial Registration and Listing; Form FDA 3741 Registration and Product Listing for Owners and Operators of Domestic Establishments (Electronic and Paper submissions); Section 905(b), (c), (d), (h), or (i).	100	1	100	1.6	160
Tobacco Product Establishment Renewal Registration and Listing; Form FDA 3741 Registration and Product Listing for Owners and Operators of Domestic Establishments (Electronic and Paper submissions); Section 905(b), (c), (d), (h), or (i).	3,578	1	3,578	0.16 (10 minutes)	572
Tobacco Product Listing; Form FDA 3742 Listing of Ingredients (Electronic and Paper submissions); Section 904(a)(1).	10	1	10	2	20
Tobacco Product Listing; Form FDA 3742 Listing of Ingredients (Electronic and Paper submissions); Section 904(c).	35	2	70	0.40 (24 minutes)	28
Obtaining a Dun and Bradstreet D–U–N–S Number.	100	1	100	0.5 (30 minutes)	50
Total					830

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The PRA burden estimates have been updated to fully incorporate the use of an electronic system known as FURLS for submitting registration and product listing information to FDA. With the FURLS, manufacturers can enter information quickly and easily. For example, product label pictures can be uploaded directly. We anticipate that most, if not all companies, already have electronic versions of their labels for printing, sales, or marketing purposes.

Product listing information is provided at the time of registration. Currently, registration and listing requirements only apply to domestic establishments engaged in the manufacture, preparation, compounding, or processing of a tobacco product. This includes importers to the extent that they engage in the manufacture, preparation, compounding, or processing of a tobacco product, including repackaging or otherwise changing the container, wrapper, or labeling of any tobacco product package. Foreign establishments are not required to register and list until FDA issues regulations establish such requirements in accordance with section 905(h) of the FD&C Act. To account for the foregoing, we include both domestic manufacturing establishments and importers in our estimates.

Because the deadline for initial establishment registration and product listing for both statutorily regulated and deemed products has passed, FDA estimates that few (up to 100) new establishments will submit 1 initial establishment registration and product listing report each year. Such new establishments potentially include new vape shop locations that mix or assemble products on the market as of the final deeming rule effective date. The Agency estimates that up to 100 tobacco establishments will each submit 1 initial establishment registration and product listing report each year, which is expected to take 1.6 hours, for a total 160 burden hours.

FDA estimates that the confirmation or updating of establishment registration and product listing information as required by section 905 of the FD&C Act will take 10 minutes annually per confirmation or update per establishment. Based on FDA's experience with current establishment registration and product listings submitted to the Agency, the Agency estimates that on average 3,578 establishments will each submit 1 confirmation or updated report each year, which is expected to take 0.16 hour (10 minutes) for a total 572 burden hours.

FDA estimates that we have received most tobacco product ingredient submissions for large manufacturers of deemed products. Small manufacturers' deadline for ingredient submissions is November 2018. This is based on the counts we have to date (July 2018), including statutorily regulated products (based on information in our tracking system).

FDA estimates that the submission of ingredient listings required by section 904(a)(1) of the FD&C Act for each establishment will take 2 hours initially. Because this burden estimate covers a timeframe of 3 years, we anticipate almost all section 904(a)(1) tobacco ingredient submissions to have been received before the expiration of the current approval (prior to November 8, 2018, for small manufacturers and for large manufacturers, May 8, 2018). We are estimating approximately 30 manufacturers may miss their deadline. This is based on estimates of how many large manufacturers we are aware of that have missed their deadline. Because this burden estimate covers 3 years, we are dividing by 3, to yield 10 respondents as a yearly average for this estimate. Therefore, FDA estimates that 10 establishments will initially submit 1 report annually at 2 hours per report, for a total of 20 hours.

Submissions under 904(c) of the FD&C Act are for any new product that is not yet on the market (*e.g.,* if on the market due to deeming compliance period); newly deemed product manufacturers should have submitted under section 904(a)(1) of the FD&C Act. This includes any statutorily regulated product that would receive a marketing authorization and any new deemed product not subject to the deeming compliance period. For deemed product categories, while we anticipate receiving a large number of premarket applications, there is a portion of these applicants who will have reported their

ingredients under section 904(a)(1) as most of these submissions are expected to be for products subject to the deeming compliance period.

Based on FDA's experience and the actual number of product ingredient listings submitted over the past 3 years, FDA estimates that 35 establishments will each submit 2 reports (1 every 6 months). FDA also estimates that the confirmation or updating of product (ingredient) listing information required by section 904(c) of the FD&C Act is expected to take 0.40 hour (24 minutes) and will take 48 minutes annually for two confirmations or updates per establishment, for a total 28 burden hours. FDA estimates that obtaining a DUNS (data universal numbering system) number will take 30 minutes. FDA assumes that all new establishment facilities that will be required to initially register under section 905 of the FD&C Act would obtain a DUNS number. FDA estimates that up to 100 establishments would need to obtain this number each year. The total industry burden to obtain a DUNS number is 50 hours.

FDA estimates the total burden for this collection to be 830 hours. We have adjusted our burden estimate, which has resulted in a decrease of 93,086 hours to the currently approved burden. Based on data we reviewed from the past 3 years and projecting the number of remaining establishments that have not registered and submitted product ingredient listings, we revised the number of respondents and burden hours in this information collection.

Dated: May 9, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–09997 Filed 5–14–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Information Collection Request Title: HRSA Ryan White HIV/AIDS Program AIDS Education and Training Centers Evaluation Activities, OMB No. 0915–0281—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than June 14, 2019.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: HRSA Ryan White HIV/AIDS Program AIDS Education and Training Centers Evaluation Activities: (OMB No. 0915–0281) Revision.

Abstract: The RWHAP AETC program, authorized by Title XXVI of the Public Health Service Act, supports a network of regional and national centers that conduct targeted, multidisciplinary education and training programs for health care providers serving people living with HIV (PLWH). The purpose of the RWHAP AETC program is to increase the size and strengthen the skills of the current and novice HIV clinical workforce in the United States and to develop and disseminate information on treatment and prevention of HIV to at-risk populations. Through the provision of specialized professional education and training, the RWHAP Regional AETCs aim to improve outcomes along the HIV care continuum including diagnosis, linkage, retention, and viral suppression and to reduce HIV incidence by improving the achievement and maintenance of viral load suppression of PLWH. In addition, the RWHAP AETC program includes the National Coordinating Resource Center (NCRC), which offers a virtual library of online training resources for adaptation by HIV care providers and other healthcare professionals to meet local training needs. The RWHAP AETC NCRC works closely with the HRSA HIV/AIDS Bureau (HAB) to coordinate cross-regional collaborative efforts, manage the NCRC website, plan and execute the national RWHAP Clinical Conference, and develop an online curriculum for clinical learners.

The RWHAP AETC proposes several revisions to the Event Records (ER) and the Participant Information Form (PIF). The ER will have 11 new data elements; however, only 7 data elements will require responses from all respondents. The option to respond to the other four data elements will depend on how participants respond to previous questions. There are four data element deletions to the ER.

The PIF will have one new data element that asks whether respondents prescribe antiretroviral therapy to their patients. Two data elements were deleted. These revisions reflect changes in the National AETC program guidance on reporting sources of funding and multi-session events.

Despite a net increase of eight data elements across both the ER and PIF instruments, pilot respondents reported a decrease in burden. HRSA HAB modified the data instruments to help inform the evaluation of AETC outcomes, improve the logical flow of questions within each instrument and to improve the overall clarity of each of the questions being asked.

A 60-day **Federal Register** Notice was published in the **Federal Register** on December 18, 2018, vol. 83, No. 242; pp. 64845–47. There were no public comments.

Need and Proposed Use of the Information: As part of an ongoing effort to evaluate RWHAP AETC activities, information is needed on AETC training sessions, clinical consultations, and technical assistance activities. Each regional center collects information on RWHAP AETC training events and is required to report aggregate data on their activities to HRSA's HAB. The goal of national data collection efforts is to create a uniform set of data elements that will produce an accurate summary of the national scope of RWHAP AETC professional training, consultation, and events. The elements included in the national database have been selected for their relevance in demonstrating the RWHAP AETCs' efforts in achieving the program's stated goals: To improve care for PLWH by providing education, training, and clinical consultation; and to provide support to clinicians and other providers. HRSA HAB uses the data collected when conducting programmatic assessments and to determine future program needs. The national data elements are intended to be a meaningful core set of elements that individual RWHAP AETCs can use in programmatic and strategic planning. HRSA HAB also uses this information to