FOR FURTHER INFORMATION CONTACT: Lillian A. Sparks Robinson, Commissioner, Administration for Native Americans, at 202–401–5590, by email at *Lillian.sparks@acf.hhs.gov,* or by mail at 370 L'Enfant Promenade SW., 2 West, Washington, DC 20447.

SUPPLEMENTARY INFORMATION: On November 5, 2009, President Obama signed the ''Memorandum for the Heads of Executive Departments and Agencies on Tribal Consultation.'' The President stated that his Administration is committed to regular and meaningful consultation and collaboration with tribal officials in policy decisions that have tribal implications, including, as an initial step, through complete and consistent implementation of Executive Order 13175.

The United States has a unique legal and political relationship with Indian tribal governments, established through and confirmed by the Constitution of the United States, treaties, statutes, executive orders, and judicial decisions. In recognition of that special relationship, pursuant to Executive Order 13175 of November 6, 2000, executive departments and agencies are charged with engaging in regular and meaningful consultation and collaboration with tribal officials in the development of federal policies that have tribal implications and are responsible for strengthening the government-to-government relationship between the United States and Indian tribes.

HHS has taken its responsibility to comply with Executive Order 13175 very seriously over the past decade; including the initial implementation of a Department-wide policy on tribal consultation and coordination in 1997, and through multiple evaluations and revisions of that policy, most recently in 2010. ACF has developed its own agency-specific consultation policy that complements the Department-wide efforts.

The ACF Tribal Consultation Session will begin on the morning of September 14, 2015, and continue throughout the day until all discussions have been completed. To help both tribal officials and the ACF Principals prepare for this consultation, planning teleconference calls will be held on:

Wednesday, August 19, 2015, 3 p.m.–3:30 p.m. Eastern Time

Wednesday, August 26, 2015, 3 p.m.–3:30 p.m. Eastern Time

Wednesday, September 2, 2015, 3 p.m.–3:30 p.m. Eastern Time

The call-in number is: 866–769–9393. The passcode is: 4449449#.

The purpose of the planning calls will be to identify individuals who will provide oral testimony to ACF, solicit for tribal moderators and identify specific topics of interest so we can ensure that all appropriate individuals are present.

Testimonies are to be submitted no later than September 8, 2015, to: Lillian Sparks Robinson, Commissioner, Administration for Native Americans, 370 L'Enfant Promenade SW., Washington, DC 20447, *anacommissioner@acf.hhs.gov.*

To facilitate the security process when entering our building, we would appreciate if participants register for the session by sending an email to *anacommissoner@acf.hhs.gov* with the names of attendees, titles, and tribe/organization name. If you plan to provide testimony, please include the name of the office(s) you wish to address. We are also interested in collecting the same information from anyone who will be attending by webinar.

Dated: July 21, 2015.

Mark H. Greenberg,

Acting Assistant Secretary for Children and Families.

[FR Doc. 2015–18430 Filed 7–27–15; 8:45 am]

BILLING CODE 4184–34–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.

DATES: Fax written comments on the collection of information by August 27, 2015.

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: 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: 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 President signed the Tobacco Control Act (Pub. L. 111–31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 301 *et seq.*) by, among other things, adding 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.

Section 905(b) of the FD&C Act (21 U.S.C. 387e(b)), as amended by the Tobacco Control Act, requires that ''every person who owns or operates any establishment in any State engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products . . .'' register with FDA the name, places of business, and all establishments owned or operated by that person. Every person must register by December 31 of each year. Section 905(c) of the FD&C Act requires that first-time persons ''engaging in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products shall register with the Secretary the name, places of business, and all such establishments of that person.'' Section 905(d) states that persons required to register under section 905(b) or (c) shall register any additional establishment that they own or operate in any State which begins the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products. Section 905(h)

addresses foreign establishment registration requirements, which will go into effect when regulations are issued by the Secretary. Section 905(i)(1) of the FD&C Act, as amended by the Tobacco Control Act, requires that all registrants ''shall, at the time of registration under any such subsection, file with [FDA] a list of all tobacco products which are being manufactured, prepared, compounded, or processed by that person for commercial distribution,'' along with certain accompanying consumer information, such as all labeling and a representative sampling of advertisements. Section 904(a)(1) of the FD&C Act (21 U.S.C. 387d(a)(1)), as amended by the Tobacco Control Act, requires each tobacco product manufacturer or importer, or agent thereof, to submit ''a listing of all ingredients, including tobacco, substances, compounds, and additives that are * * * added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand or by quantity in each brand and subbrand.'' Since the Tobacco Control Act was enacted on June 22, 2009, the information required under section 904(a)(1) must be submitted to FDA by December 22, 2009, and include the ingredients added as of the date of submission. Section 904(c) of the FD&C Act also requires submission of information whenever additives, or the quantities of additives, are changed.

FDA issued guidance documents on both: (1) Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments and (2) listing of Ingredients in Tobacco Products to assist persons making such submissions to FDA under the Tobacco Control Act. While electronic submission of registration and product listing information and ingredient listing information are not required, FDA is strongly encouraging electronic submission to facilitate efficiency and timeliness of data management and collection. To that end, FDA designed electronic submission applications to streamline the data entry process for registration and product listing and for ingredient listing. These tools allow for importation of large quantities of structured data, attachment of files (*e.g.,* in portable document format (PDFs) and certain media files), and automatic acknowledgement of FDA's receipt of submissions.

FDA also developed paper forms (Form FDA 3741—Registration and Listing for Owners and Operators of Domestic Tobacco Product Establishments, and Form FDA 3742—Listing of Ingredients in Tobacco Products) as an alternative submission tool. Both the electronic submission application and the paper forms can be accessed at *http://www.fda.gov/tobacco*.

In the **Federal Register** of April 21, 2015 (80 FR 22202), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

FDA Form/activity/TCA section	Number of respondents	Number of responses per respondent	Total annual responses	Hours per response	Total hours	Total operating and maintenance costs
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).	135	1	135	2	270	$0.66
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).	135	1	135	0.20 (12 minutes).	27	0.66
Tobacco Product Initial Ingredient Listing; Form FDA 3742 Listing of Ingredients (Electronic and Paper submissions); Section 904(a)(1) or (c).	135	1	135	2	270	0.66
Tobacco Product Renewal Ingredient Listing; Form FDA 3742 Listing of Ingredients (Electronic and Paper submissions); Section 904(a)(1) or (c).	135	2	270	0.40 (24 minutes).	108	1.32
Obtaining a Dun and Bradstreet D–U–N–S Number	8	1	8	0.5	4	
Tobacco Product Ingredient Listing Electronic and Paper submission	135	1	135	3	405	0.66
Total					1,084	3.96

On April 21, 2015, the FDA published a 60-day notice (80 FR 22202) requesting public comments in the **Federal Register**. In this notice, the total amount of burden hours for this collection was incorrectly listed as 1,354 hours. After an internal review of burden for this collection, FDA realized that the burden in the 60-day **Federal Register** notice did not take into account new information from another Federal Agency (which revised the number of respondents slightly upward), and the use of a new electronic registration and product listing submission system. To correct this oversight, FDA is revising the number of respondents upward, from 125 to 135 respondents. FDA also has incorporated the use of a new electronic system into this collection, so the total hours were revised from 1,354 hours to 1,084 hours in table 1.

The burden estimates have been updated to fully incorporate the use of FDA's new electronic system known as FURLS for submitting registration and product listing information to FDA. This system allows companies to enter information quickly and easily. For example, product label pictures can be uploaded directly into the system and FDA anticipates that most, if not all companies already have electronic versions of their labels for printing, sales, or marketing purposes. FDA anticipates that the initial entry registration and initial product listing will each take 2 hours per entity.

Under section 905, once information is entered into FURLS, the twice yearly conformation or updates to product lists are expected to be simplified as all information previously entered is maintained and visible in the system. Therefore, FDA expects that ongoing maintenance of the product listing information will take 30 minutes twice a year, or a total of 1 hour annually. This is broken down into 12 minutes for recurring Registration and Listing each year, and 24 minutes twice a year for recurring Product Ingredient Listings, or a total of 48 minutes annually.

Based on data shared by another Federal Agency, FDA estimates that 135 establishments will initially submit one report, and then will submit confirmation or update reports on a semiannual basis.

FDA estimates that the confirmation or updating of registration information as required by section 905 will take 12 minutes annually per confirmation or update per establishment.

FDA estimates that the submission of product listings required by section 905 for each establishment will take 2 hours initially. FDA also estimates that the confirmation or updating of product listing information required by section 905 will take 48 minutes annually for two confirmations or updates per establishment.

FDA estimates that obtaining an optional Dun and Bradstreet D–U–N–S number will take 0.5 hours, and that 8 respondents (1 percent × 135 = 1.35 of establishments required to register under section 905, and 5 percent × 135 = 6.75 of submitters required to list ingredients under section 904) will not already have a Dun and Bradstreet D–U–N–S number.

FDA estimates that the submission of ingredient listing information as required by section 904 of the act will take 3 hours per tobacco product.

Dated: July 22, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–18410 Filed 7–27–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–2537]

Request for Quality Metrics; Notice of Draft Guidance Availability and Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting; notice of draft guidance availability, request for comments.

SUMMARY: The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER), is announcing the availability of a draft guidance for industry entitled ''Request for Quality Metrics'' and a public meeting regarding the Agency's plans associated with a quality metrics reporting program. The draft guidance and public meeting are intended to gain stakeholders' perspectives on various aspects of the development and planned implementation of a quality metrics program launched under the authority of the Food, Drug, and Cosmetic Act (the FD&C Act). The guidance includes an explanation of how FDA intends to use quality metrics data to further develop the FDA's risk-based inspection scheduling, to identify situations in which there may be a risk for drug supply disruption, to improve the efficiency and effectiveness of establishment inspections, and to improve FDA's evaluation of drug manufacturing and control operations. FDA expects that the initial use of the metrics will be to consider a decreased surveillance inspection frequency for certain establishments. For example, establishments that have highly controlled manufacturing processes have the potential to be inspected less often (as a lower priority for inspection) than similar establishments that demonstrate uncontrolled processes (as a higher priority for inspection). In addition, FDA intends to consider whether these metrics may provide a basis for FDA to use improved risk-based principles to determine the appropriate reporting category for postapproval manufacturing changes. FDA intends to consider the input from this public meeting as we finalize this guidance and the planned implementation of this program, including FDA's initial set of requests for quality metrics data.

DATES: The meeting will be held on August 24, 2015, from 8:30 a.m. to 5 p.m. The meeting may be extended or end early depending on the level of public participation. Register to attend or present at the meeting by August 7, 2015, (see section V.C. for information on how to register or make a presentation at the meeting). If you cannot attend in person, information about how you can access a live Web cast will be located at *http://www.fda.gov/Drugs/NewsEvents/ucm451529.htm.*

Submit either electronic or written comments concerning the draft guidance and collection of information proposed in the draft guidance by September 28, 2015.

ADDRESSES: The meeting will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503 Section B/C), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–7800.

Submit electronic comments on the draft 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. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Althea Cuff, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–4061, email: *Althea.Cuff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

More than a decade ago, FDA launched an initiative to encourage the implementation of a modern, risk-based pharmaceutical quality assessment system. As part of this initiative, and in recognition of the increasing complexity of pharmaceutical manufacturing, FDA developed a 21st century vision for manufacturing and quality with input from academia and industry. The desired state was described as follows: ''A maximally efficient, agile, flexible pharmaceutical manufacturing sector that reliably produces high-quality drug products without extensive regulatory oversight.'' [1]

There has been significant progress toward this vision in the intervening

[1] See ''FDA Pharmaceutical Quality Oversight: One Quality Voice'' at *http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM442666.pdf.*