

Tobacco Product Establishment Registration and Listing

0910-0650

SUPPORTING STATEMENT

Terms of Clearance: None

A. Justification

1. Circumstances Making the Collection of Information Necessary

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111-31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (the 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 many requirements for the tobacco industry. Section 101 of the Tobacco Control Act amended the act by adding sections 905 and 904.

Registration and Listing (Section 905)

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 has delegated to the Commissioner of the Food and Drug Administration the responsibility for administering the act, including section 905.

Section 905 of the act requires owners or operators of each establishment to register:

- 1) their name (905(b))
- 2) places of business (905(b))
- 3) a list of all tobacco products which are manufactured by that person (905(i)(1))
- 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 or to premarket review under section 910 (905(i)(1)(A))
- 5) a copy of all consumer information and other labeling (905(i)(1)(B))
- 6) a representative sampling of advertisements(905(i)(1)(B))
- 7) upon request made by the Secretary for good cause, a copy of all advertisements for a particular tobacco product (905(i)(1)(B))
- 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, a brief statement of the basis upon which the registrant made such determination (905(i)(1)(C)).

FDA collects the information submitted pursuant to section 905 through an electronic portal, and through a paper form (Form FDA 3741) for those individuals who choose not to use the electronic portal. In the electronic portal and paper form FDA is requesting the following information:

- Registrant information
 - role of registrant
- Owner information
 - owner name, title, address, email, and position title
 - company name, address, telephone & fax number, owner Dun and Bradstreet D-U-N-S number (optional), any other owner company business name, type of business structure, list of corporate officers and director, and state of incorporation
- Establishment information
 - establishment name, address, telephone & fax number, establishment Dun and Bradstreet D-U-N-S number (optional), and functions performed by establishment
- Operator information
 - Operator name, address, operator Dun and Bradstreet D-U-N-S number (optional), any other operator business name, type of business structure, name of individuals associated with business structure, and state of incorporation
- Product listing, details
 - unique product name, intended use, category, and flavor
- Product listing, labeling
 - all labeling for each product including identification of type of labeling, internal identification number, UPC code, and date label was first published
- Product listing, consumer information
 - all consumer information for each product including type of material, internal identification number, and date material was first disseminated
- Product listing, advertising
 - a representative sampling of advertising for each product including type of advertising material, internal identification number, and date advertisement was first disseminated
- Confirmation statement
 - certification of truth and accuracy
 - authorized agent name, title, address, email, and position title
 - authorized agent company name, address, and telephone & fax number.

FDA has also published a guidance for industry entitled “Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments.” This guidance is intended to assist persons making tobacco product establishment registration and product listing submission to FDA.

Ingredient Listing (Section 904)

Section 904(a)(1) of the 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 act requires that a tobacco product manufacturer: 1) Provide all information required under section 904(a) 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 the 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 the FDA through regulation as not a human or animal carcinogen, or otherwise harmful to health under intended conditions of use; 3) Advise the 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 the 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 section 904(a)(1) and 904(c) through an electronic portal, and through a paper form (Form FDA 3742) for those individuals who choose not to use the electronic portal. In the electronic portal and paper form, FDA is requesting the following information:

- Type of submission
 - new submission, ingredient listing for tobacco products on the market as of June 22, 2009
 - new submission, ingredient listing for new tobacco product
 - update to previous submission to add, delete, or change the quantity of an additive
- Manufacturer (or importer) identification
 - submitter type, company name, address, country, company headquarters Dun and Bradstreet D-U-N-S number (optional), and company headquarters FEI number
- point of contact for this submission
 - Contact name, title, position title, mailing address, email, telephone, and fax
- Tobacco product identification
 - FDA assigned tracking number, tobacco product brand/sub-brand name or other commercial name, product identification number, type of product identification number, intended use of product, consumer use product category, further manufacturing use product category, and flavor
- Ingredient listing
 - product name, FDA assigned tracking number, ingredient number, and alternative ingredient using the ingredient number
 - ingredient identification,
 - for a single chemical substance: unique scientific name or code, type of code, and identification of reaction product

- for leaf tobacco: type, variety, cure method, heat source, and identification of genetic or transgenic manipulation
- for complex purchased ingredients: manufacturers name, unique identifying item name and or numbers used by manufacturer, and identification if ingredient is made to submitter's specifications
- ingredient details including quality, expected functions, and part ingredient is added to
- quantity of ingredient including unit of measurement and how quantity is determined, limit of detection, quantity of additive increase or decrease with date of change, or date of introduction to market
- Confirmation statement
 - identification and signature of submitter including name, company name, address, position title, email, telephone, and fax.

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.

D-U-N-S Number

The FDA Standards Council has designated Dun and Bradstreet's Data Universal Numbering System (D-U-N-S®) Number as the business entity standard, to be used along with FDA's internal tracking numbers. Electronic registration for submitting Registration and Listing and Product Identifier information now will accept a DUNS number and it can be used as an optional Center for Tobacco Products (CTP) registration number. However, the DUNS number is not required to be used for CTP transactions. Obtaining a DUNS number allows each business to be uniquely identified by FDA, and is specific for each corporate entity and place of business.

Deeming tobacco products

The Food and Drug Administration (FDA) issued a final rule to deem products meeting the statutory definition of "tobacco product" to be subject to the Federal Food, Drug, and Cosmetic Act (FD&C Act). The FD&C Act provides FDA authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and any other tobacco products that the Agency by regulation deems to be subject to the law. This final rule extends the Agency's "tobacco product" authorities to all other categories of products that meet the statutory definition of "tobacco product" in the FD&C Act, except accessories of such newly deemed tobacco products. This final rule also prohibits the sale of "covered tobacco products" to individuals under the age of 18 and requires the display of health warnings on cigarette tobacco, roll-your own tobacco, and covered tobacco product packages and in advertisements. The rule also provides that manufacturers, distributors, importers, and retailers are responsible for ensuring that the covered tobacco products (in addition to cigarettes and smokeless tobacco) they manufacture, label, advertise, package, distribute,

import, sell, or otherwise hold for sale comply with all applicable requirements. FDA is taking this action to reduce the death and disease from tobacco products.

2. Purpose and Use of the Information Collection

FDA will use the information collected under these provisions of the act to meet inspection requirements, and the information will inform FDA's development of good manufacturing practices and review standards for new tobacco products, among others.

The information collected by FDA will be used to register new and update existing tobacco product establishments required under section 905 of the act and to register new product ingredient listings, and update existing product ingredient listing required under sections 904(a)(1) and 904(c) of the act. The collection of the DUNS number information is optional, and the information can be used by FDA to identify tobacco establishments who must comply with the act.

If this data is not able to be collected, FDA would be unable to effectively regulate portions of the Tobacco Control Act.

Respondents to this collection are expected to be tobacco product establishment for-profit businesses or their representatives from the private sector.

3. Use of Improved Information Technology and Burden Reduction

FDA has chosen to collect the required information through electronic portals and through paper forms for those individuals who choose not to use the electronic portals. In April 2014, FDA launched a new web-based registration and listing system, the FDA Unified Registration and Listing System (FURLS). FURLS allows establishments to upload and view their data at any time. Establishments no longer need to download an electronic submission program to their computers, can submit their information online from the website; can update files for product labeling, advertising, and consumer information without resubmitting the entire listing; and can report no changes to their registration or product listing by simply checking a box.

FDA estimates that approximately 99% of the respondents will use the electronic portals to fulfill the agency's request for registration and listing, and product ingredient listing. For the purposes of calculating burden in Item 12, 100% of respondents will be assumed to use FDA's electronic portal to submit registration and listing and product ingredient listing information.

4. Efforts to Identify Duplication and Use of Similar Information

This information collection is not duplicative and the Tobacco Control Act requires the submission of this information. FDA is the only Federal agency responsible for the collection of such information, and is the primary federal regulatory authority with respect to

the manufacture, marketing, and distribution of tobacco products. Therefore, no duplication of data exists.

FDA also has extensive contacts with other agencies that have collected or are currently collecting tobacco data, and no similar registration and listing or product ingredient listing data is known to be available to respondents of this collection of information.

5. Impact on Small Businesses or Other Small Entities

The information submission requirements in sections 905 and 904 do not fall disproportionately upon small businesses as the Tobacco Control Act requires the submission of this information from all owners and operators of a tobacco product establishment. FDA is providing an alternative paper form for those individuals who are unable, or choose not to, use the electronic portals. FDA continues to pursue means of reducing the reporting burden for both small and large respondents and will continue to employ the latest technology for receiving these submissions, consistent with the intent of the legislation.

FDA aids small business in dealing with the information submission requirements of sections 905 and 904 by providing guidance, which further describes the statutory requirement, for submitting this information. FDA also offers assistance to small businesses through its office of Small Business Assistance, and FURLS Support.

6. Consequences of Collecting the Information Less Frequently

The Tobacco Control Act requires the registration information submission under section 905 of the act to be completed annually by December 31 of each year. As of the effective date of the deeming rule, those persons who own or operate domestic manufacturing establishments engaged in manufacturing newly deemed tobacco products (including those that engage in the blending of pipe tobacco and the mixing of e-liquids) will be required to register with FDA and submit product listings under section 905. This deeming rule will not require foreign manufacturing establishments to register their establishments or to list their tobacco products in order to sell them in the United States. However, foreign manufacturing establishments will be required to comply with the registration and listing requirements of section 905 of the FD&C Act after a registration and listing rule is final and effective.

A less frequent collection of information would not satisfy the requirements of the act. The Tobacco Control Act requires the ingredient listing information submission under section 904(a)(1) of the act to be completed by December 22, 2009 and submissions under 904(c) to be submitted according to a clearly identified timeline. A less frequent collection of this information would also not satisfy the requirements of the act.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

As required by section 3506(c)(2)(B) of the Paperwork Reduction Act of 1995 (PRA), FDA provided an opportunity for public comment on the information collection requirements of the proposed rule that published in the FEDERAL REGISTER of April 25, 2014 (79 FR 23142). FDA has responded to the comments received in the preamble to the final rule, and the supporting statement for the Deeming information collections under OMB control number 0910-0768.

9. Explanation of Any Payment or Gift to Respondents

This information collection does not provide for any payment or gift to respondents.

10. Assurance of Confidentiality Provided to Respondents

Among the laws governing the disclosure of registration and listing data submitted under section 905 of the act are the Freedom of Information Act (FOIA) (5 U.S.C. 552) and section 905(f) of the act (21 U.S.C. 387e(f)), as well as FDA's implementing regulations. Under FOIA, the public has broad access to agency records, unless the records (or a part of the records) are protected from disclosure by any of the law's nine exemptions. Under section 905(f) of the act, FDA shall make available for inspection, to any person so requesting, any registration filed under section 905 of the act.

Information submitted under section 904 of the act may include, but is not limited to, a company's non-public trade secret or confidential commercial information. Several laws govern the confidentiality of ingredient information submitted under section 904 of the act, including sections 301(j) and 906(c) of the act (21 U.S.C. 331(j) and 387f(c)), the Trade Secrets Act (18 U.S.C. 1905), and the Freedom of Information Act (FOIA) (5 U.S.C. 552), as well as FDA's implementing regulations.

Section 906(c) of the act prohibits FDA from disclosing any information reported to or otherwise obtained by FDA under section 904, among other provisions, if that information is confidential commercial or trade secret information exempt from disclosure under FOIA Exemption 4 (5 U.S.C. 552(b)(4)). The provision contains exceptions allowing disclosure of the information to other officers or employees concerned with carrying out the tobacco products chapter of the act and, when relevant, in any proceeding under the tobacco products chapter of the act. Section 301(j) of the act generally prohibits release of trade secret information obtained by FDA under section 904, among other provisions, outside of the Department of Health and Human Services, except to courts when relevant in any judicial proceeding under the act and to Congress in response to an authorized Congressional request.

FDA's general regulations concerning the public availability of FDA records are contained in 21 CFR Part 20.

11. Justification for Sensitive Questions

This information collection does not contain questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

FDA estimates the burden for this information collection as follows:

Table 1.--Estimated Annual Reporting Burden					
FDA Form/ Activity/TCA Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
Tobacco Product Establishment Initial Registration and Listing; FDA Form 3741 Registration and Product Listing for Owners and Operators of Domestic Establishments (Electronic and Paper submissions); Sections 905(b), 905(c), 905(d), 905(h), or 905(i)	4,880	1	4,880	1.6	7,808
Tobacco Product Establishment Renewal Registration and Listing; FDA Form 3741 Registration and Product Listing for Owners and Operators of Domestic Establishments (Electronic and Paper submissions); Sections 905(b), 905(c), 905(d), 905(h), or 905(i)	4,880	1	4,880	.16(10 min)	781
Tobacco Product Initial Listing; FDA Form 3742 Listing of Ingredients (Electronic and Paper submissions); Sections 904(a)(1) or 904(c)	4,880	1	4,880	2	9,760

FDA Form/ Activity/TCA Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
Tobacco Product Renewal Listing; FDA Form 3742 Listing of Ingredients (Electronic and Paper submissions); Sections 904(a) (1) or 904(c)	4,880	2	9760	0.40 (24 mins)	3,904
Obtaining a Dun and Bradstreet D-U-N-S Number	4,768	1	4,768	0.5	2,385 ¹
Tobacco Product Ingredient Listing electronic and paper submission	766	8.45 ²	6,473	3	19,425
Tobacco Product Ingredient Listing electronic and paper submission (Vape shops that qualify as manufacturers) ³	4,250	11.73	49,853	1	49,853
Total			0		93,916

¹This number is rounded

²This number is rounded

³ FDA assumes that vape shops will register and list only during the first two years after the rule becomes effective.

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 and we anticipate that most, if not all companies, already have electronic versions of their labels for printing, sales, or marketing purposes.

In addition to the 120 respondents for pre deemed products, there are 113 domestic manufacturers of cigars, 216 importers of cigars, 74 domestic manufacturers of pipe (including waterpipe) tobacco, and 43 importers of pipe (including waterpipe) tobacco who will be required to register under section 905 of the FD&C Act based on aggregate information obtained from the Alcohol and Tobacco Tax and Trade Bureau (TTB). For the purposes of this analysis, FDA estimates that the majority of the 4,250 vape shops who that qualify as manufacturers will only register and list in the first two years after the rule becomes effective. In addition, FDA estimates that 186 ENDS manufacturers will be required to register under section 905 of the FD&C Act.

FDA estimates that 4,880 establishments will each initially submit one report, and then will submit confirmation or update reports on a semi-annual basis. Based on FDA's

experience and the actual number of registrations submitted over the past three years, and new aggregate data from TTB, the agency estimates that 4,880 tobacco establishments will each submit 1 registration, which is expected to take 1.6 hours, for a total 7,808 burden hours.

FDA estimates that the confirmation or updating of registration information as required by section 905 will take 10 minutes annually per confirmation or update per establishment. Based on FDA's experience and the actual number of registrations submitted over the past three years, and aggregate data from TTB, the agency estimates that 4,880 establishments will each submit one report every year and each submission is expected to take 0.16 hours (10 minutes) for a total 781 burden hours.

Under section 905, once information is entered into FURLS, the yearly confirmation of annual registration and product listing updates is simplified as all information previously entered is maintained in the system. Therefore, we expect the recurring burden of subsequent years for updating registration and product listing information will take 58 minutes annually. This is broken down into 10 minutes for recurring Registration and Listing each year, and 12 minutes twice a year for recurring Product Ingredient Listings, or a total of 56.7 minutes annually. The total hours are 4,685 (781 updating registration and 3,904 product listing).

The estimate for the number of product listing submissions for cigars is derived by using product counts from two retail Web sites: <http://www.cigarsinternational.com/> and <http://www.pipesandcigars.com/>. These two large Internet retailers had larger product offerings than other sites reviewed and sell both mass-market and specialty products. Estimates of product formulations and product-package combinations for cigars are derived from the product counts from the two Web sites. To derive the product listing count for pipe tobacco, we count the products on a Web site with a broad product offering, <http://www.pipesandcigars.com/>. We estimate formulations using the number of product names and product-packages with the number of product-package combinations. FDA derives the product listing estimate for ENDS products by consulting experts at FDA's Center for Tobacco Products who cataloged the ENDS products currently available on five Web sites and in scanner data from Nielsen.

FDA estimates that the submission of product listings required by section 905 for each establishment will take 2 hours initially and forty-eight minutes a year for confirming or updating the information. FDA estimates that 4,880 establishments will initially submit one report annually, and then will submit two confirmations or update reports semi-annually. Based on FDA's experience and the actual number of product ingredient listings submitted over the past three years, the agency estimates that 4,880 tobacco establishments will initially submit 1 tobacco product listing and that each submission should take approximately 2 hours. The total burden hours are 9,760 burden hours.

FDA also estimates that the confirmation or updating of product listing information required by section 905 will take forty-eight minutes annually for two confirmations or updates per establishment. FDA estimates that 4,880 establishments will each submit two reports (one every six months). Based on FDA's experience and the actual number of product ingredient

information submitted over the past three years, the agency estimates that approximately 2 product ingredient submissions will be submitted from 4,880 tobacco product establishments annually. Each submission is expected to take 0.40 hours (twenty-four minutes) for a total 3,904 hour burden hours.

FDA estimates that obtaining a DUNS number will take 30 minutes. FDA assumes that all the establishment facilities that will be required to register under section 905 of the FD&C Act would obtain a DUNS number, with a total of 4,760 establishments that would need to obtain this number for deemed products and 8 for currently regulated products for a total of 518. The total burden to obtain a DUNS number is 2,385 hours.

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.¹ Foreign establishments are not required to register and list until FDA issues regulations establishing 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. Specifically, for the PRA analysis, we have used the midpoint between TTB permit counts for manufacturers and permit counts for manufacturers and importers as a likely overestimate of the number of entities that need to comply with registration and product listing.

The Agency estimates that approximately 56,326 (6,473 year three and beyond since FDA assumes that vape shops will register and list only during the first two years after the rule becomes effective) ingredient listings/annual responses will be submitted annually based on the methodology used for estimating the number of product listing submissions described in this section and on the actual number of product ingredient listings submitted over the past 3 years. FDA estimates that the total burden for tobacco product establishment registration and ingredient listing reporting is 69,278 hours.

FDA estimates the total burden for this collection to be 93,916.

12b. Annualized Cost Burden Estimate

The annual reporting cost to respondents for registering establishments is \$5,165,380. These figures were derived by multiplying the total reporting burden hours (93,916 hours) by an hourly rate of \$55. This hourly rate is based on a 2,080 annual work hours and at an annual

¹ Under the Internal Revenue Code, the manufacture, preparation, compounding, or processing of a tobacco product may require a permit as a manufacturer of tobacco products. As we understand TTB's permitting requirements, entities lacking a manufacturer permit, including importers, may not engage in any of the listed activities, including repackaging tobacco products after such products are released from customs custody. It is unclear whether TTB would require a manufacturer permit for all activities for which FDA would determine the entity must register and list; because there may be some entities with import permits for which FDA would conclude registration is necessary, FDA includes those numbers as part of its upper-bound estimate of affected entities.

salary rate of \$116,000. This health care professional salary rate includes salary, benefits, overhead, technical staff, support staff, etc. This annual rate was determined by the Agency’s current estimates of staff expenses.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Tobacco Product Establishment Employees	93,916	\$55.00	\$5,165,380
Total			\$5,165,380

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

The capital costs associated with this collection pertain to the postage cost for mailing the form for those individuals who choose not to use the electronic portal and are estimated to be \$419 (rounded). This estimate is based upon 855 responses (1% of 85,494 total responses) being submitted via U.S. first class mail and the cost of a first class postage stamp at \$ 0.49. Start-up and capital costs refer to purchases that the respondent would not make in the absence of this information collection request or requirement.

14. Annualized Cost to the Federal Government

FDA anticipates that the Federal Government will incur the following costs:

Staff Costs

Full time Equivalentents = 8
 Annual Cost per FTE = \$116,000
 Total Annual Cost = \$928,000

As noted above, FDA anticipates that 2 FTEs will maintain the electronic portals, and 6 FTE’s will review, process, and approve applications submitted to the system or submitted on paper form under this collection of information.

15. Explanation for Program Changes or Adjustments

This is a non-substantive change request to include a revised version of the associated Registration and Listing guidance. OMB has concurred with the submission of this change request. Based on the new compliance policy, FDA estimates a decrease of 2,591hours.. The new total burden hours are estimated to be 93,916. FDA has also updated the burden charts to remove information from a previous revision that is no longer necessary.

16. Plans for Tabulation and Publication and Project Time Schedule

FDA does not intend to publish the results of this information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA is not requesting an exemption for display of the OMB expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions to the certification statement were identified.