Tobacco Product Establishment Registration and Listing

0910-0650

SUPPORTING STATEMENT

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 Act) by adding among other things, a new 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 new requirements for the tobacco industry. Section 101 of the Tobacco Control Act amended the act by adding, among other things, sections 905 and 904.

Registration and Listing

Section 905 of the 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 published a guidance intended to assist persons making tobacco product establishment registration and product listing submission to FDA on November 12, 2009 (74 FR 58298).

Ingredient Listing

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 ingredient listing submission.

Section 904(c) of the act requires that a tobacco product manufacturer: 1) Provide all information required under section 904(a) "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
- Submitter identification
    - submitter type, company name, address, country, company headquarters Dun and Bradstreet D-U-N-S number (optional), and company headquarters FEI number
- Submitter point of contact
    - Contact name, title, position title, 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 electronic portal and paper form, FDA published a guidance intended to assist persons making tobacco product establishment registration ingredient listing submissions. (See 74 FR 62795; December 1, 2009) For further assistance FDA provides a technical guide, embedded hints, and a web tutorial to the electronic portal.

In the future FDA may publish a separate electronic tool and paper form for the collection of information identified under 904(c). If a separate 904(c) system is developed FDA will seek OMB approval of that form.

D-U-N-S Number

The FDA Standards Council has designated Dun and Bradstreet's DUNS 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.

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 will inform FDA's development of good manufacturing practices and review standards for new tobacco products, among others.

The annual information collected by FDA is used to register new and 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 D-U-N-S number information collected is optional, and 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 normally tobacco product establishment for- profit businesses from the private sector.

3. Use of Improved Information Technology and Burden Reduction

FDA has chosen to collect the required information through an electronic portal and through a paper form for those individuals who choose not to use the electronic portal. FDA estimates that approximately 99% of the respondents will use the electronic portal 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 be using the 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. 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.

5. Impact on Small Businesses or Other Small Entities

The approximate number of entities (125) responding to this collection of information are businesses. The information submission requirements in sections 905 and 904 do not fall disproportionately upon small businesses. 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 portal. 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 will further describe the statutory requirement, for submitting this information (see 74 FR 58298 and 74 FR 62795). FDA also offers assistance to small businesses through its office of Small Business Assistance and/or the eSubmitter Help Desk.

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. 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 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

   In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the FEDERAL REGISTER of May 3, 2012 (77 FR 26281). One comment was received which discussed the importance of extending this collection. This comment was beyond the scope of this collection..

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 906(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:

Estimated Annual Reporting Burden[1]

FDA Form/ Activity/TCA Section	No. of Respondents	Annual Frequency per Response	Total Annual Respondents	Hours per Response	Total Hours
Form FDA 3742 Registration and Product Listing for Owners and Operators of Domestic Establishments (Electronic and Paper submission) Sections 905(b), 905(c), 905(d), 905(h), or 905(i)	125	1.6	200	3.75	750
Form FDA 3473 Listing of Ingredients (Electronic and Paper submissions) Sections 904(a)(1) or 904(c)	125	1.6	200	3.0	600
Obtaining a Dun and Bradstreet D-U-N-S Number (10%	8	1	8	0.5	4

of total respondents)					
Total					1,354

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

FDA estimates that the submission of registration information as required by section 905 of the act will take 3.75 hours per establishment. Based on the actual number of registration information submitted over the past two years and its experience, the agency estimates that approximately 200 registrations will be submitted from 125 tobacco product establishments annually, for a total 750 hour burden (125 respondents x 1.6 responses per respondent x 3.75 hours per response).

FDA estimates that the submission of ingredient listing information as required by section 904 of the act will take 3.0 hours per tobacco product. Based on the actual number of product ingredient listings submitted over the past 2 years and its experience, the agency estimates that approximately 200 ingredient listings will be submitted from 125 tobacco establishments, for a total 600 burden hours (125 respondents x 1.6 responses per respondent x 3.0 hours per response).

FDA estimates that obtaining an optional Dun and Bradstreet D-U-N-S number will take 0.5 hours, and that 8 respondents (1% (1.25) of establishments required to register under section 905 and 5% (6.25) of submitters required to list ingredients under section 904) will not already have a Dun and Bradstreet D-U-N-S number. The total burden, therefore, will be 4 hours (8 respondents x 1 response per respondent x 0.5 hours per response).

12b. Annualized Cost Burden Estimate

The annual reporting cost to respondents for registering establishments is $77,470. These figures were derived by multiplying the total reporting burden hours (1,354 hours) by an hourly rate of $55. This hourly rate is based on a 2,080 annual work hours and at an annual 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	1,354	$55.00	$77,470
Total			$77,470

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

$1.80. This estimate is based upon 4 responses (1% of 400 total responses) being submitted via U.S. first class mail and the cost of a first class postage stamp at $ 0.45.

14. Annualized Cost to the Federal Government

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

Staff Costs
Total annual cost to the Federal Government = $696,000

Full time Equivalents = 8
Annual Cost per FTE=$116,000
Annual Cost = $928,000

As noted above, FDA anticipates that 2 FTEs will maintain the eSubmitter Registration and Listing System, 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

There has been an adjustment to the burden for this collection of information. The collection has decreased by 407,721 hours, from 409,075 to 1,354 hours. This is a result of experience that FDA has gained over the past two years in the regulation of tobacco products and is based on the actual number of submissions received. In 2010, FDA attempted to determine the actual number of tobacco manufacturers through the use of the Security and Exchange Commission's Standard Industrial Classification (SIC) codes, which are identifying codes that appear in a company's EDGAR filings to indicate the company's type of business. The tobacco industry SIC codes indicated that over 10,000 tobacco manufacturers existed for tobacco products and cigarettes. Upon further examination, it appears that the number of tobacco manufacturers was greatly inflated, as the SIC codes included tobacco retailers in addition to tobacco manufacturers. Also, no comments were received from the 2010 package's 60 Day Federal Register Notice regarding either the number of respondents or the number of reporting burden hours listed in the notice, so FDA used the collection's SIC-researched manufacturer numbers for the collection of information. Registration and listing, and product listing report numbers were recently scrutinized by FDA, and it was discovered that in the past two years, the number of tobacco manufacturers required to register their products and ingredient listings is approximately 125, a substantial decrease from the number of potential respondents listed in 2010. By applying the revised number of manufacturers to the burden chart in Item 12, the total burden for registration and listing now is 1,354 burden hours, much less than the 409,075 OMB-approved burden hours stated in 2010.

FDA's burden estimate for tobacco product establishment registration under section 905 remains at 3.75 hours per response. FDA's estimate for ingredient listing under section 904 remains at 3.0 hours per response.

Based on the actual number of registration and product listing and product ingredient listing reports received, the number of expected annual responses is projected to decrease substantially, from 100,000 registration and listing responses to 200 annual responses, and

from 11,000 annual product ingredient listing responses to 200 annual product ingredient listings. The total number of annual burden hours for this collection of information is expected to decrease by 407,721 hours, from 409,075 hours to 1,354 hours.

The agency has based its estimate on the actual number of registration and listing and product ingredient listing reports received, its experience with the submission of registration and listing requirements applicable to other FDA regulated products, and on-going interactions with industry.

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.