Tobacco Product Establishment Registration and Ingredient 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 new 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 creates many new requirements for the tobacco industry. Section 101 of the Tobacco Control Act amends the act by adding, among other things, new sections 905 and 904.

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, 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, and functions performed by establishment
- Operator information
  - Operator name, address, operator Dun and Bradstreet D-U-N-S number, 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).

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, 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 will provide 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.

2. Purpose and Use of the Information Collection

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

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. We estimate that approximately 99% of the respondents will use the electronic portal.

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 the primary federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products. Therefore, no duplication of data exists.

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. 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).

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 information would not satisfy the requirements of the act.

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

This section is not applicable.

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

On September 1, 2009 (74 FR 45219), FDA published notice in the Federal Register announcing that a proposed collection of information had been submitted to OMB for emergency processing under the Paperwork Reduction Act of 1995. On September 15, 2009 (74 FR 47257), FDA published a notice correcting the length of the comment period, keeping it open until October 1, 2009. On October 13, 2009 (74 FR 52495), FDA published a notice reopening the comment period until October 26, 2009. Comments in response to the emergency processing were sent directly to OMB. FDA is aware of several comments filed in response to this information collection.

Based on preliminary comments indicating that the burden estimate was too low, FDA adjusted its original burden estimate. FDA adjusted its burden estimate for tobacco product establishment registration under section 905 from 0.75 hours per response to 3.75 hours per response. FDA has adjusted its burden estimate for ingredient listing under section 904 from 0.75 hours per response to 3.0 hours per response.

The 60-day notice announcing an opportunity for public comment on the revised estimates was published on February 18, 2010 (75 FR 7269). FDA received one comment that was outside the scope of the notice.

The new burden estimate is reflected in other sections of this document.

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

On September 1, 2009 (74 FR 45219), FDA published notice in the Federal Register announcing that a proposed collection of information had been submitted to OMB for emergency processing under the Paperwork Reduction Act of 1995. On September 15, 2009 (74 FR 47257), FDA published a notice correcting the length of the comment period, keeping it open until October 1, 2009. On October 13, 2009 (74 FR 52495), FDA published a notice reopening the comment period until October 26, 2009. Comments in response to the emergency processing were sent directly to OMB. FDA is aware of several comments filed in response to this information collection. Accordingly, FDA adjusted its burden estimate for this information collection request. FDA solicited public comment for 60-days on February 18, 2010, on the information collection renewal (75 FR 7269).). FDA received one comment that was outside the scope of the notice.

Hour Burden Estimate
FDA estimates the burden for this information collection as follows:

Estimated Annual Reporting Burden

Activity	No. of Respondent	Annual Frequency per Response	Total Annual Respondents	Hours per Response	Total Hours

	s				
Tobacco Product Establishment Registration (electronic)	99,000	1	99,000	3.75	371,250
Tobacco Product Establishment Registration (Form 3741)	1,000	1	1,000	3.75	3,750
Tobacco Product Ingredient Listing (electronic)	10,990	1	10,990	3.0	32,970
Tobacco Product Ingredient Listing (Form 3742)	110	1	110	3.0	330
Obtaining a Dun and Bradstreet D-U-N-S Number	1,550	1	1,550	0.5	775
Total	112,650		112,650		408,775

FDA estimates that the submission of registration information as required by section 905 of the act will take 3.75 hours per establishment. The agency estimates that approximately 100,000 registrations will be submitted. The agency bases its estimate on its experience with the submission of registration and listing requirements applicable to other FDA regulated products.

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. The agency estimates that approximately 11,000 ingredient listings will be submitted. The agency bases its estimate on the total number of tobacco products it is aware of and its experience with the other submission using the electronic portal.

FDA estimates that obtaining a Dun and Bradstreet D-U-N-S number will take 0.5 hours. FDA 1% (1,000) of establishments required to register under section 905 and 5% (550) of submitters required to list ingredients under section 904 will not already have a Dun and Bradstreet D-U-N-S number.

Reporting Cost Burden Estimate
The annual reporting cost to respondents for registering establishments is $22,482,625. These figures were derived by multiplying the total reporting burden 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.

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

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 $488.00. This estimate is based upon 1,110 responses (1% of 110,000 total responses) being submitted via U.S. first class mail and the cost of a first class postage stamp at $ 0.44.
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 = 6

Annual Cost per FTE=$116,000

Annual Cost = $696,000

15. Explanation for Program Changes or Adjustments

FDA adjusted its burden estimate for tobacco product establishment registration under section 905 from 0.75 hours per response to 3.75 hours per response. FDA also adjusted the burden estimate for ingredient listing under section 904 from 0.75 hours per response to 3.0 hours per response. Both of these increases resulted in an adjustment in the total burden in the amount of 300 hours. The $4.00 increase in the annual cost burden is due to a slight increase in the number of respondents estimated to send in the paper form FDA 3742.

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.