4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0386]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [**INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**].

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	No. of Respondents	No. 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.

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