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 (PRA).

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: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, 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 Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111-31) was signed into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (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 new requirements for the tobacco industry. Section 101 of the Tobacco Control Act amended the FD&C Act by adding sections 905 and 904 (21 U.S.C. 387e and 387d).

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 (Secretary) has delegated to the Commissioner of Food and Drugs the responsibility for administering the FD&C Act, including section 905. Section 905 of the FD&C Act requires owners or operators of each establishment to register: (1) their name; (2) places of business; (3) a list of all tobacco products that are manufactured by that person; (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 of the FD&C Act (21 U.S.C. 387g) or to premarket review under section 910 of the FD&C Act (21

U.S.C. 387j); (5) a copy of all consumer information and other labeling; (6) a representative sampling of advertisements; (7) upon request made by the Secretary for good cause, a copy of all advertisements for a particular tobacco product; and (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 of the FD&C Act, a brief statement of the basis upon which the registrant made such determination.

FDA collects the information submitted pursuant to section 905 of the FD&C Act through an electronic portal, and through paper forms (Forms FDA 3741 and FDA 3741a) for those individuals who choose not to use the electronic portal.

FDA has also published a guidance for industry entitled "Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments" (https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM191940.pdf). This guidance is intended to assist persons making tobacco product establishment registration and product listing submissions to FDA.

Section 904(a)(1) of the FD&C 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 FD&C Act requires that a tobacco product manufacturer: (1) provide all information required under section 904(a) of the FD&C Act 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 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 FDA through regulation as not a human or animal carcinogen, or otherwise harmful to health under intended conditions of use; and (3) advise 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 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 sections 904(a)(1) and (c) of the FD&C Act through an electronic portal, and through a paper form (Form FDA 3742) for those individuals who choose not to use the electronic portal.

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.

The Tobacco Control Act also gave FDA the authority to issue a regulation deeming all other products that meet the statutory definition of a tobacco product to be subject to chapter 9 of the FD&C Act (section 901(b) (21 U.S.C. 387a(b)). On May 10, 2016, FDA issued that rule, extending FDA's tobacco product authority to all products that meet the definition of tobacco product in the law (except for accessories of newly regulated tobacco products), including electronic nicotine delivery systems, cigars, hookah, pipe tobacco, nicotine gels, dissolvables that

were not already subject to the FD&C Act, and other tobacco products that may be developed in the future (81 FR 28974 at 28976) ("the final deeming rule").

In the *Federal Register* of October 23, 2018 (83 FR 53478), FDA published a 60-day notice requesting public comment on the proposed collection of information. Two comments were received; however, neither were PRA related.

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

Table 1.--Estimated Annual Reporting Burden[1]

FDA Form/Activity/FD&C Act Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
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)	100	1	100	1.6	160
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)	3,578	1	3,578	0.16 (10 minutes)	572
Tobacco Product Listing; Form FDA 3742 Listing of Ingredients (Electronic and Paper submissions); Section 904(a)(1)	10	1	10	2	20
Tobacco Product Listing; Form FDA 3742 Listing of Ingredients (Electronic and Paper submissions); Section 904(c)	35	2	70	0.40 (24 minutes)	28
Obtaining a Dun and Bradstreet D-U-N-S Number	100	1	100	0.5 (30 minutes)	50
Total					830

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

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

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. Foreign establishments are not required to register and list until FDA issues regulations establish 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.

Because the deadline for initial establishment registration and product listing for both statutorily regulated and deemed products has passed, FDA estimates that few (up to 100) new establishments will submit 1 initial establishment registration and product listing report each year. Such new establishments potentially include new vape shop locations that mix or assemble products on the market as of the final deeming rule effective date. The Agency estimates that up to 100 tobacco establishments will each submit 1 initial establishment registration and product listing report each year, which is expected to take 1.6 hours, for a total 160 burden hours.

FDA estimates that the confirmation or updating of establishment registration and product listing information as required by section 905 of the FD&C Act will take 10 minutes annually per confirmation or update per establishment. Based on FDA's experience with current establishment registration and product listings submitted to the Agency, the Agency estimates

that on average 3,578 establishments will each submit 1 confirmation or updated report each year, which is expected to take 0.16 hour (10 minutes) for a total 572 burden hours.

FDA estimates that we have received most tobacco product ingredient submissions for large manufacturers of deemed products. Small manufacturers' deadline for ingredient submissions is November 2018. This is based on the counts we have to date (July 2018), including statutorily regulated products (based on information in our tracking system).

FDA estimates that the submission of ingredient listings required by section 904(a)(1) of the FD&C Act for each establishment will take 2 hours initially. Because this burden estimate covers a timeframe of 3 years, we anticipate almost all section 904(a)(1) tobacco ingredient submissions to have been received before the expiration of the current approval (prior to November 8, 2018, for small manufacturers and for large manufacturers, May 8, 2018). We are estimating approximately 30 manufacturers may miss their deadline. This is based on estimates of how many large manufacturers we are aware of that have missed their deadline. Because this burden estimate covers 3 years, we are dividing by 3, to yield 10 respondents as a yearly average for this estimate. Therefore, FDA estimates that 10 establishments will initially submit 1 report annually at 2 hours per report, for a total of 20 hours.

Submissions under 904(c) of the FD&C Act are for any new product that is not yet on the market (e.g., if on the market due to deeming compliance period); newly deemed product manufacturers should have submitted under section 904(a)(1) of the FD&C Act. This includes any statutorily regulated product that would receive a marketing authorization and any new deemed product not subject to the deeming compliance period. For deemed product categories, while we anticipate receiving a large number of premarket applications, there is a portion of

these applicants who will have reported their ingredients under section 904(a)(1) as most of these submissions are expected to be for products subject to the deeming compliance period.

Based on FDA's experience and the actual number of product ingredient listings submitted over the past 3 years, FDA estimates that 35 establishments will each submit 2 reports (1 every 6 months). FDA also estimates that the confirmation or updating of product (ingredient) listing information required by section 904(c) of the FD&C Act is expected to take 0.40 hour (24 minutes) and will take 48 minutes annually for two confirmations or updates per establishment, for a total 28 burden hours. FDA estimates that obtaining a DUNS (data universal numbering system) number will take 30 minutes. FDA assumes that all new establishment facilities that will be required to initially register under section 905 of the FD&C Act would obtain a DUNS number. FDA estimates that up to 100 establishments would need to obtain this number each year. The total industry burden to obtain a DUNS number is 50 hours.

FDA estimates the total burden for this collection to be 830 hours. We have adjusted our burden estimate, which has resulted in a decrease of 93,086 hours to the currently approved burden. Based on data we reviewed from the past 3 years and projecting the number of remaining establishments that have not registered and submitted product ingredient listings, we revised the number of respondents and burden hours in this information collection.

Dated: May 9, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-09997 Filed: 5/14/2019 8:45 am; Publication Date: 5/15/2019]