



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No.FDA-2012-D-0049]

Agency Information Collection Activities; Proposed Collection; Comment Request; Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information associated with the reporting of harmful and potentially harmful constituents in tobacco products and tobacco smoke under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2012-D-0049 for the information collection request entitled “Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under the Federal Food, Drug, and Cosmetic Act.”

Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions -- To submit a comment with confidential information that you do not wish to be made publicly available submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility,

and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and
Tobacco Smoke Under the Federal Food, Drug, and Cosmetic Act
(OMB Control Number 0910-0732)--Extension

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Public Law 111–31) into law. This law amended the FD&C Act and granted FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health generally and to reduce tobacco use by minors. Section 904(a)(3) of the FD&C Act (21 U.S.C. 387d(a)(3)) required each tobacco product manufacturer or importer, or an agent, to begin reporting to FDA no later than June 22, 2012, “all constituents, including smoke constituents, identified by [FDA] as harmful or potentially harmful to health in each tobacco product, and as applicable in the smoke of each tobacco product.” Reports must be by the brand and by quantity in each brand and subbrand. Section 904(c)(1) of the FD&C Act states that manufacturers of tobacco products not on the market as of June 22, 2009, must also provide information reportable under section 904(a)(3) at least 90 days prior to introducing the product into interstate commerce.

FDA has taken several steps to identify harmful and potentially harmful constituents (HPHCs) to be reported under sections 904(a)(3) and (c)(1) of the FD&C Act, including issuing a guidance discussing FDA’s current thinking on the meaning of the term "harmful and potentially harmful constituent" in the context of implementing the HPHC list requirement under section 904(e) of the FD&C Act (76 FR 5387, January 31, 2011). The guidance is available on the

Internet at

<http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm241339.htm>. In addition, in the Federal Register of April 3, 2012 (77 FR 20034), FDA published a notice (the HPHC list notice) announcing the established list of HPHCs as required by section 904(e) of the FD&C Act and describing the criteria we used in identifying the HPHCs for the established list. Previously, FDA sought comment on both the criteria that would be used to identify HPHCs for the established list and a list of chemicals and chemical compounds that met the proposed criteria.

The purpose of the information collection is to collect statutorily mandated information regarding HPHCs in tobacco products and tobacco smoke, by quantity in each brand and subbrand.

To facilitate the submission of HPHC information, FDA has developed Forms 3787a, 3787b, and 3787c in both paper and electronic formats. Manufacturers or importers, or their agents, may submit information either electronically or in paper format. The FDA eSubmitter tool provides electronic forms to streamline the data entry and submission process for reporting HPHCs. Users of eSubmitter may populate an FDA-created Excel file and import data into eSubmitter. Whether respondents decide to submit reports electronically or on paper, each form provides instructions for completing and submitting HPHC information to FDA. The forms contain fields for company information, product information, and HPHC information.

Respondents finished reporting initial HPHC information under section 904(a)(3) in 2012, and this collection of information is in connection with the reporting requirements under section 904(c)(1) of the FD&C Act for tobacco products introduced into interstate commerce after June 22, 2009.

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

Table 1.--Estimated Annual Reporting Burden¹

Information Collected	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Reporting for Section 904(c)(1) Products					
1. Reporting of Manufacturer Company and Product Information by Completing Submission Forms					
Cigarette	78	0.79	62	1.82	113
Roll-Your-Own	39	0.21	8	0.43	3
Smokeless	52	0.21	11	0.63	7
Total					123
2. Testing of HPHC Quantities in Products					
Cigarette Filler	78	0.79	62	9.42	584
Roll-Your-Own	39	0.21	8	9.42	75
Smokeless	52	0.21	11	12.06	133
Total					792
3. Testing of HPHC Quantities in Mainstream Smoke					
Cigarette: International Organization for Standardization (ISO) Regimen	78	0.79	62	23.64	1,466
Cigarette: Health Canada Regimen	78	0.79	62	23.64	1,466
Total					2,932
Total Section 904(c)(1) Reporting Burden Hours					3,847

¹ There are no capital costs or operating costs associated with this collection of information.

Table 1 contains estimates for new product information received annually under section 904(c)(1) of the FD&C Act. Manufacturers must report HPHC information under section 904(c)(1) of the FD&C Act at least 90 days prior to delivery for introduction into interstate commerce. The total annual burden for this collection of information is estimated to be 3,847 hours. The burden estimate for this collection of information includes the time it will take to test the products and prepare the HPHC report.

Table 1 indicates that 169 respondents will submit HPHC reports when new products enter the market. Section 1 of the table addresses the time required for manufacturers to report their company information. We estimate that the time to report HPHC information is no more than 1.82 hours for cigarettes, 0.42 hours for roll-your-own, and 0.63 hours for smokeless

tobacco products for each response regardless of whether the paper or electronic form (Form FDA 3787) is used. (The estimated times to report smokeless tobacco products (0.63 hour) and roll-your-own tobacco products (0.43 hour) are lower than the estimated reporting time for cigarette products because fewer HPHCs are normally reported for these two types of products. The total annual burden for reporting company and product information is 123 hours.

Section 2 of the table addresses the time required for manufacturers to test quantities of HPHCs in their products. The burden hour estimates include the time needed to test the tobacco products, draft testing reports, and draft the report for FDA. For cigarette filler, smokeless, and roll-your-own products, we estimate the burden to be 792 annual burden hours. The burden for each product type reflects our estimate of the time to test the tobacco products (i.e., carry out laboratory work).

In addition to addressing the time required to report information and test quantities of HPHCs in tobacco products, section 3 of table 1 addresses the time required for manufacturers to test quantities of HPHCs in cigarette smoke. The burden estimates include testing the tobacco products, drafting testing reports, and drafting the report for FDA. We estimate the annualized burden for this section to be 2,932 hours. The annual burden reflects our estimate to test the tobacco products (i.e., carry out laboratory work). The burden estimate assumes that manufacturers report HPHC quantities in cigarette mainstream smoke according to the two smoking regimens described in the table.

The estimated total annual burden for the reporting of HPHC under section 904(c)(1) of the FD&C Act is 3,847 hours. We do not believe there are any capital costs associated with this collection.

Dated: November 6, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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