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<NOTICE>

<PREAMB>

4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under 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 oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-NEW and title "Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under the Federal Food, Drug, and Cosmetic Act." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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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.

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

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Public Law 111–31) into law. This law amends the Federal Food, Drug, and Cosmetic Act (FD&C Act) and grants 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)) requires 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 final guidance discussing FDA's current thinking on the meaning of "harmful and potentially harmful constituent" in the context of implementing the HPHC list requirement (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.

In the Federal Register of April 3, 2012 (77 FR 20030), FDA announced the availability of a draft guidance entitled "Guidance for Industry: Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under Section 904(a)(3) of the Federal Food, Drug, and Cosmetic Act" (904(a)(3) draft guidance) discussing the information to be reported on HPHCs in tobacco products and tobacco smoke under sections 904(a)(3) and (c)(1) of the FD&C Act. The 904(a)(3) draft guidance discusses, among other things: The statutory requirement for testing and reporting quantities of HPHCs, who tests and reports quantities of HPHCs to FDA, what HPHCs will be the focus of FDA enforcement at this time, when reports are submitted to FDA, what information is reported to FDA, and how the reports should be

submitted to FDA. The 904(a)(3) draft guidance notifies manufacturers and importers that, at this time, while industry is developing laboratory capacity to comply with section 904(a)(3) of the FD&C Act, FDA does not intend to enforce the statutory requirement to submit quantities of all constituents identified by FDA as HPHCs by June 22, 2012, where manufacturers or importers complete testing and reporting for an abbreviated list of HPHCs as set forth in the 904(a)(3) draft guidance. In particular, at this time, for products that were first marketed before June 22, 2012, FDA does not intend to enforce the section 904(a)(3) requirement to test and report quantities of all HPHCs on FDA's established list where: (1) A manufacturer or importer (or agents thereof), other than a small tobacco product manufacturer, submits quantities of the HPHCs on an abbreviated list described in the guidance for all of its products, by brand and subbrand, no later than September 22, 2012 or (2) a small tobacco product manufacturer (or agents thereof) submits quantities of HPHCS on the abbreviated list for all of its products, by brand and subbrand, by December 22, 2012. In addition, for products first marketed on or after June 22, 2012, the 904(a)(3) draft guidance explains that FDA does not intend, at this time, to enforce the requirement in section 904(c)(1) of the FD&C Act to test and report quantities of all HPHCs on FDA's established list for products not previously on the market if a manufacturer or importer reports quantities for the abbreviated list of HPHCs at least 90 days prior to marketing the product in the United States. The 904(a)(3) draft guidance explains that, at this time, FDA intends to enforce the HPHC reporting requirements with respect to manufacturers of finished tobacco products for consumer use--cigarettes, smokeless tobacco, and roll-your-own tobacco--and not with respect to manufacturers and importers of other products, such as components sold to manufacturers or consumers for incorporation into finished products.

The purpose of the proposed information collection is for FDA to collect statutorily mandated information regarding HPHCs in tobacco products and tobacco smoke, by quantity in each brand and subbrand. The 904(a)(3) draft guidance provides an abbreviated list of HPHCs on which FDA intends to focus enforcement at this time for each of the following: Cigarette smoke, smokeless tobacco products, and roll-your-own tobacco and cigarette filler.

To facilitate the submission of HPHC information, FDA has developed Form 3787 in both paper and electronic formats. Manufacturers or importers, or an agent, 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 also populate an Excel file and import data into eSubmitter. FDA also provides paper forms for the submission of section 904(a)(3) reports. FDA placed draft copies of the paper forms and screen shots of the electronic form and spreadsheet in this docket. Whether respondents decide to submit reports electronically or on paper, each form provides instructions for filling out and submitting HPHC information to FDA. The forms contain fields for company information, product information, and HPHC information (including the specific HPHCs identified in the 904(a)(3) draft guidance).

The Federal Register notice announcing the availability of the 904(a)(3) draft guidance included a 60-day notice requesting public comment on the proposed collection of information. FDA received 16 comments that were PRA-related, including but not limited to the following issues:

- Suggestions to enhance the quality, utility, and clarity of the information to be collected (i.e., comments specific to FDA's eSubmitter tool and paper forms);

- Cost associated with the collection of information to comply with section 904(a)(3) of the FD&C Act, particularly for small tobacco product manufacturers; and
- Use of the proposed information collection, especially because specific test methods are not prescribed to determine HPHC quantities.

Section 904(a)(3) of the FD&C Act requires HPHC testing and reporting. We have stated that we intend to exercise enforcement discretion for manufacturers who test for 20 rather than 93 HPHCs at this time. In addition, we have recognized that small tobacco product manufacturers are likely to rely on contract testing laboratories and intend to exercise enforcement discretion for those who submit quantities of HPHCs 6 months after the statutory deadline (i.e., December 22, 2012), and 3 months after submissions by other tobacco product manufacturers. Our abbreviated list of HPHCs, along with the timeframes described in the draft guidance, represent a reasonable approach to implementing section 904(a)(3) of the FD&C Act.

Based on comments received, FDA has revised the instructions for FDA Form 3787 to explain that if the HPHC quantity is below the limit of detection or limit of quantitation, zero should be entered in the space identified for form. We have also made minor cosmetic changes to clarify instructions and to allow accurate data entry. FDA has not revised the burden estimate for this collection of information.

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
Part 1-- Section 904(a)(3) of the FD&C Act (Annualized estimate of one-time reporting) ²					
1. Reporting of Manufacturer/Importer Company and Product Information by Completing Submission Forms					
Cigarette	120	10.10	1,212	2	2,424
Roll-Your-Own	46	3.22	148	2	296

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
Smokeless	200	1.44	288	2	576
Total					3,296
2. Testing of HPHC Quantities in Products					
Cigarette Filler	120	10.1	1,212	9.42	11,417
Roll-Your-Own	46	3.22	148	9.42	1,394
Smokeless	200	1.44	288	12.06	3,473
Total					16,284
3. Testing of HPHC Quantities in Mainstream Smoke					
Cigarette: International Organization for Standardization (ISO) Regimen	120	10.1	1,212	23.64	28,652
Cigarette: Health Canada Regimen	120	10.1	1,212	23.64	28,652
Total					57,304
Total Section 904(a)(3) Annualized One-Time Burden					
76,884					
Part 2-- Reporting of Section 904(c)(1) New Products (15% of One-Time Burden Totals) ³					
1. Reporting of Manufacturer/Importer Company and Product Information by Completing Submission Forms					
Cigarette	18	10.10	182	2	364
Roll-Your-Own	7	3.22	23	2	46
Smokeless	30	1.44	43	2	86
Total					496
2. Reporting of HPHC Quantities in Products					
Cigarette Filler	18	10.1	182	9.42	1,714
Roll-Your-Own	7	3.22	23	9.42	217
Smokeless	30	1.44	43	12.06	519
Total					2,450
3. Reporting of HPHC Quantities in Mainstream Smoke					
Cigarette: ISO Regimen	18	10.1	182	23.64	4,302
Cigarette: Health Canada Regimen	18	10.1	182	23.64	4,302
Total					8,604
Total Section 904(c)(1) Burden					
11,550					
Total Reporting Burden Hours					
88,434					

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

² One-time actual first year burden hours have been annualized over the 3-year OMB period of approval to avoid over counting the burden each year.

³ Annual new product reporting under section 904(c)(1) of the FD&C Act is estimated to be 15 percent of the annualized one-time burden.

FDA estimates the one-time reporting burden for this guidance would be 230,652 hours during the first year for section 904(a)(3) of the FD&C Act reporting plus ongoing annual burden of 11,550 hours for section 904(c)(1) reporting. The burden estimate for this collection of

information includes the time it will take to read the guidance document, test the products, and prepare the HPHC report.

To avoid overcounting the one-time reporting burden, FDA has annualized the one-time burden over the 3-year expected OMB period of approval. The annualized one-time burden of 76,884 hours is located in part one of table 1 of this document, and includes burden for collections of information gathered under section 904(a)(3) of the FD&C Act. The total annual burden for this collection of information is estimated to be 88,434 hours, which is the annualized one-time burden estimate for section 904(a)(3) of the FD&C Act associated with the submission of HPHC reports and the annual burden estimate for section 904(c)(1). Table 1 of this document estimates 366 respondents will submit HPHC reports on a one-time basis. Table 1 of this document addresses the time required for manufacturers and importers to report their company information. We estimate that the burden is no more than 2 hours per response to report company and product information, regardless of whether the paper or electronic form (Form FDA 3787) is used. This estimate is not dependent on product type, so the estimated burden is the same for cigarettes, roll-your-own tobacco, and smokeless tobacco products. We also estimate that 3,636 cigarette subbrands, 445 roll-your-own tobacco subbrands, and 861 smokeless tobacco subbrands (4,942 total subbrands) must comply with section 904(a)(3) of the FD&C Act. Therefore, the total annualized burden for reporting company and product information is 3,296 hours.

Table 1 of this document also addresses the time required for manufacturers and importers to report quantities of HPHCs in their products. The burden hour estimates include the time needed to test the tobacco products, draft testing reports, draft the report for FDA, and submit the report to FDA. For cigarette filler, smokeless, and roll-your-own products, we estimate the burden to test the product, draft testing reports, draft the report for FDA, and submit

the report to FDA to be 16,284 annualized burden hours. The burden for each product type reflects our estimate of the burden to test the tobacco products (i.e., carry out laboratory work).

In addition to addressing the time required to report quantities of HPHCs in tobacco products, table 1 of this document addresses the time required for manufacturers and importers to report quantities for HPHCs in cigarette smoke. The burden estimates include testing the tobacco products, drafting testing reports, drafting the report for FDA, and submitting the report to FDA. We estimate the annualized burden for this section to be 57,304 hours. The annualized burden reflects our estimate of the burden to test the tobacco products (i.e., carry out laboratory work). The burden estimate assumes that manufacturers and importers report HPHC quantities in cigarette mainstream smoke according to the two recommended smoking regimens. The total annualized burden for part one of table 1 (section 904(a)(3) reporting) is 76,884 hours.

Table 1 of this document also contains estimates for new product information received annually under section 904(c)(1) of the FD&C Act. Manufacturers and importers 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. We estimate that approximately 15 percent of FDA currently regulated tobacco products in any given year will require submission of this information. The estimated total annual burden for section 904(c)(1) of the FD&C Act is 11,550 hours, which includes reporting manufacturer/importer company and product information, reporting HPHC quantities in products, and reporting HPHC quantities in mainstream smoke.

The estimated total annual burden for the reporting of HPHC under section 904(a)(3) and (c)(1) of the FD&C Act is 88,434 hours, which includes the section 904(a)(3) annualized reporting burden plus the section 904(c)(1) annual reporting burden.

We have not estimated any capital costs because we do not believe there are any capital costs associated with this collection. However, you may comment on any specific capital costs that you have identified.

Dated: July 24, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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