



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Draft Guidance for Industry: Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under the Federal Food, Drug, and Cosmetic Act; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under Section 904(a)(3) of the Federal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.” The purpose of this draft guidance is to assist persons reporting to FDA the quantities of harmful and potentially harmful constituents (HPHCs) in tobacco products and tobacco smoke under the Federal Food, Drug, and Cosmetic Act (the FD&C Act). The draft guidance explains that FDA does not intend, at this time, to enforce reporting on the entire established HPHC list where a manufacturer or importer completes testing and reporting for an abbreviated list of HPHCs within the timeframes specified in the guidance.

DATES: Although you can comment on any guidance at any time (21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Submit either electronic or written comments on the proposed

collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance document to the Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850-3229. Send one self-addressed adhesive label to assist that office in processing your request or a fax number to which the draft guidance may be sent. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance, including comments on the proposed collection of information to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

With regard to the draft guidance:

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With regard to the proposed collection of information:

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SUPPLEMENTARY INFORMATION:

I. Background

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) (Public Law 111-31) into law. The Tobacco Control Act amends the 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) 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 HPHCs to be reported under section 904(a)(3), 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.h](http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm241339.htm)

[tm](#). In addition, on August 12, 2011, FDA issued a document (the HPHC notice; 76 FR 50226) in the Federal Register describing the criteria we tentatively concluded we would use in identifying the HPHCs for the established list, including a table of the 96 HPHCs we identified using those criteria, and asking the public and interested parties to submit relevant scientific and other information by October 11, 2011. FDA reviewed comments received in response to the HPHC notice. Elsewhere in this issue of the Federal Register, FDA is publishing a notice announcing the established list of HPHCs as required by section 904(e) of the FD&C Act.

This draft guidance discusses the information to be reported on HPHCs in tobacco products and tobacco smoke under section 904(a)(3) of the FD&C Act. This draft guidance document 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 draft guidance notifies manufacturers and importers that at this time, while industry is developing laboratory capacity to comply with section 904(a)(3), 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 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 draft 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 draft guidance explains that FDA does not intend, at this time, to enforce the requirement in section 904(c)(1) 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. In addition, the 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.

Although this draft guidance announces an intent to exercise enforcement discretion for a limited time, FDA intends to move toward full implementation and enforcement of the statutory requirement to test and report quantities of all HPHCs on FDA's established list, as appropriate. We anticipate that this guidance will be revised or withdrawn as we move toward full implementation. We intend to use the information submitted under sections 904(a)(3) and 904(c)(1) of the FD&C Act to meet the requirements of section 904(e) of the FD&C Act regarding a list of HPHCs in each tobacco product by brand and by quantity in each brand and subbrand. Also, the information will be used to comply with section 904(d)(1) of the FD&C Act, which requires FDA to publish a list of HPHCs, by brand and by quantity in each brand and subbrand, in a format that is understandable and not misleading to lay persons.

II. Significance of Guidance

FDA is issuing this draft guidance document consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on reporting HPHCs in tobacco products and tobacco smoke under section 904(a)(3) of the FD&C Act. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (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 before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing a notice of the proposed collection of information set forth in the draft guidance for industry entitled "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."

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.

Draft 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 (OMB Control Number 0910-NEW)

The purpose of the proposed information collection is to allow FDA to collect statutorily mandated information regarding HPHCs in tobacco products and tobacco smoke, by brand and by quantity in each brand and subbrand. The 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 forms 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 intends to place 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. The draft

guidance provides an abbreviated list of HPHCs on which FDA intends to focus enforcement at this time, and information to assist in the testing and reporting of HPHCs for cigarette smoke and filler, smokeless tobacco, and roll-your-own tobacco. FDA has created forms to assist in the reporting of HPHC information for each of these product types.

Description of Respondents: The respondents to this collection of information include manufacturers or importers who complete testing and reporting for HPHCs in tobacco products and tobacco smoke under section 904(a)(3) of the FD&C Act. Respondents could also include agents of manufacturers or importers who complete HPHC testing and reporting.

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

| Table 1.--Estimated Annual Reporting Burden ¹ | | | | | |
|--|--------------------|---------------------------------|------------------------|-----------------------------|-------------|
| 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 |
| 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 | | | | | |

| Table 1.--Estimated Annual Reporting Burden ¹ | | | | | |
|--|--------------------|---------------------------------|------------------------|-----------------------------|-------------|
| Information Collected | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Average Burden per Response | Total Hours |
| 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 overcounting the burden each year.

³ Annual new product reporting under section 904(c)(1) is estimated to be 15% 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) 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 divided the first year burden by three, annualizing the one-time burden over the 3-year expected OMB period of approval to avoid double-counting the one-time projected burden. The one-time burden for year one is located in part 1 of table 1 of this document, and includes burden for collections of information gathered under section 904(a)(3). The annualized total one-time burden in part 1 of table 1 is 76,884 hours (230,652 hours divided by 3), which includes 3,296 hours for reporting manufacturer or importer company and product information, 16,284 hours for reporting HPHC quantities in products, and 57,304 hours for reporting HPHC quantities in mainstream smoke.

As shown in table 1, 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) associated with the submission of an HPHC (76,884 hours) and the annual burden estimate for section 904(c)(1) (11,550 hours). We have assumed a one-time burden for section 904(a)(3) because this draft guidance is intended to remain in effect while industry is developing laboratory capacity to comply fully with section 904(a)(3) of the FD&C Act. We also assume any new product reporting requirements under section 904(c)(1) will be provided annually to FDA. We also anticipate this guidance will be revised or withdrawn as FDA moves toward full implementation and enforcement of the statutory requirement to report quantities by brand and subbrand of all HPHCs on FDA's established HPHC list.

Part one of table 1 estimates that 366 respondents (120 cigarette manufacturers or importers, 200 smokeless manufacturers, and 46 roll-your-own tobacco manufacturers) will submit 4,942 HPHC reports on a one-time basis (e.g., 1,648 reports on an annualized basis). As noted previously, FDA estimates that it will take the manufacturer, importer, or their agents 230,652 hours on a one time basis, or 76,884 hours annually, to collect the information necessary to test the products and submit an HPHC report by brand and subbrand.

Part one, section one of table 1 addresses the time required for manufacturers and importers to report their company information: Company name; mailing address; telephone and FAX numbers; FDA Establishment Identifier (FEI) number; Data Universal Numbering System (D-U-N-S) number; and point of contact name, mailing address, and telephone and FAX numbers. The first section of table 1 also addresses the time required for manufacturers and importers to report their product information by entering testing information onto the forms: Brand and subbrand name; unique product identification number; type of product identification

number; product category and subcategory; and mean weight and standard deviation of tobacco in product. We estimate that the burden is no more than 2 hours per response to report company and product information testing 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 estimate that there are 3,636 cigarette subbrands, 445 roll-your-own tobacco subbrands, and 861 smokeless tobacco subbrands (4,942 total subbrands) that 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 (4,942 respondents X 2 hours = 9,884 one-time hours divided by 3).

Part one, section two of table 1 addresses the time required from manufacturers and importers to report quantities for HPHCs in their products: Number of replicate measurements; test date range; manufacture date range; extraction method; separation method; detection method; and mean quantity and standard deviation of HPHCs. The burden hour estimates in this section 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 draft testing reports, draft the report for FDA, and submit the report to FDA to be 48,852 one-time hours, or 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). The per-response burden for testing cigarette filler and roll-your-own tobacco is the same, as the same HPHCs must be measured for both product types. The per-response burden for testing smokeless products is greater than that for the other two product types because more HPHCs must be tested for smokeless products than the other two product types.

Part one, section three of table 1 addresses the time required for manufacturers and importers to report quantities for HPHCs in cigarette smoke: The number of replicate measurements; test date range; manufacture date range; extraction method; separation method; detection method; and mean quantity and standard deviation of HPHCs. The burden estimates include the burden to test the tobacco products, draft testing reports, draft the report for FDA, and submit the report to FDA. We estimate the one-time burden for this section to be 171,912 hours, or 57,304 annualized 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 (3,296 hours plus 16,284 hours plus 57,304 hours).

Part two of table 1 contains estimates for new product information received under section 904(c)(1). Manufacturers and importers must report HPHC information under section 904(c)(1) 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) is 11,550 hours, which includes 496 hours to report manufacturer/importer company and product information, 2,450 hours to report HPHC quantities in products, and 8,604 hours to report HPHC quantities in mainstream smoke.

The estimated total annual burden for the reporting of HPHC under sections 904(a)(3) and 904(c)(1) is 88,434 hours (76,884 annualized burden hours for section 904(a)(3) reporting plus 11,550 annual burden hours for section 904(c)(1) reporting).

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.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received documents may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Persons with access to the Internet may obtain an electronic version of this guidance document at <http://www.regulations.gov> and <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm>.

Dated: March 23, 2012.

Leslie Kux.

Assistant Commissioner for Policy.