Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Lori J. Churchyard, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Investigating and Reporting Adverse Reactions Related to Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) Regulated Solely under Section 361 of the Public Health Service Act and 21 CFR part 1271; Guidance for Industry.'' The guidance provides establishments that manufacture HCT/Ps, with recommendations for complying with the requirements for investigating and reporting adverse reactions involving communicable disease in recipients of HCT/Ps that are regulated solely under section 361 of the Public Health Service Act (PHS Act) and 21 CFR part 1271 (361 HCT/Ps).

In the **Federal Register** of February 20, 2015 (80 FR 9267), FDA announced the availability of the draft guidance of the same title dated February 2015. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. In addition, editorial changes were made to improve clarity.

The guidance supplements section XXII of FDA's guidance entitled ''Guidance for Industry: Current Good Tissue Practice (CGTP) and Additional Requirements for Manufacturers of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)'' dated December 2011 by providing additional recommendations specific to the responsibilities to investigate complaints of adverse reactions concerning 361 HCT/Ps under 21 CFR 1271.160(b)(2), 21 CFR 1271.320 and 21 CFR 1271.350(a)(1) and, supersedes the guidance entitled ''Guidance for Industry: MedWatch Form FDA 3500A: Mandatory Reporting of Adverse Reactions Related to Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)'' dated November 2005. The guidance provides updated information specific to reporting adverse reactions related to HCT/Ps to supplement the general instructions accompanying the MedWatch mandatory reporting form, Form FDA 3500A. The guidance announced in this notice finalizes the draft guidance of the same title dated February 2015.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on Investigating and Reporting Adverse Reactions Related to Human Cells, Tissues, and Cellular and Tissue-Based Products Regulated Solely under Section 361 of the Public Health Service Act and 21 CFR part 1271; Guidance for Industry. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

The guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 1271 have been approved under OMB control number 0910–0543; and the collections of information in MedWatch Form FDA 3500A has been approved under OMB control number 0910–0291.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: March 2, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–05215 Filed 3–8–16; 8:45 am]

BILLING CODE 4164–01–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 the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by April 8, 2016.

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 0910–0732. 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.

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 (Pub. L. 111–31) into law. This law amended the Food Drug and Cosmetic Act (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 as applicable, 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 sub-brand. 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 sub-brand.

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.

In the **Federal Register** of November 13, 2015 (80 FR 70232), FDA published a 60-day notice requesting public comment on the proposed collection of information. Four comments were received; however, only one was PRA related.

A comment stated that FDA has dramatically underestimated the annual number of responses that will be submitted from tobacco product manufacturers and importers. The comment contended that our estimate does not appear to be based on the Agency's experience with respect to ''new'' tobacco product submissions under section 910 of the FD&C Act.

We have reconsidered our estimates, and agree with what we understand the comment to be saying, that we have not accounted for the submission of the two streamlined alternative substantial equivalent (SE) reports, one for label changes and one for product quantity changes, referred to as the ''Same Characteristics SE Report'' and the ''Product Quantity Change SE Report,'' respectively, and subsequent premarket authorization for a ''new tobacco product'' as defined under section 910(a)(1) of the FD&C Act (21 U.S.C. 387j(a)(1)). Based on FDA data, we estimate between 500 and700 (*i.e.,* approximately 600) new tobacco products annually, as a result of manufacturers and importers submitting these streamlined submissions. We also estimate that the report of HPHC data in connection with these new tobacco products will take approximately 1 hour to prepare and submit. FDA has added a new line in the table for this category of new tobacco products.

A comment also stated that the burden estimated for testing the quantities of HPHCs in cigarette filler and roll-your-own, smokeless, and smoke as 9.42 hours, 12.06 hours and 23.64 hours respectively, per product, has been dramatically underestimated. The comment contends that HPHC testing may more realistically be expected to take 7 to 12 weeks per product. FDA does not agree with this comment. The Agency based its estimates on its understanding as to how long the tests themselves take, as opposed to the length of time between when a manufacturer or importer may first request that a test be done and then receives the test results from an internal or independent laboratory.

Furthermore, a comment stated that the burden estimated for the time required to report HPHC information to the Agency has been underestimated. The comment contends that in one entity's experience, the time required to report on the testing of a cigarette may be expected to take around 200 hours, taking into account the time required to compile the requisite information and to complete, review and edit the associated form.

FDA disagrees with this comment as we believe the estimates for testing the quantities of HPHCs are accurate. Additionally, we note that the comment did not contain any data to support its contention.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Information collected	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Reporting for Section 904(c)(1) Products					
1. Reporting of Manufacturer/Importer 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 (26 minutes)	3
Smokeless	52	0.21	11	0.63 (38 minutes)	7

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Information collected	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
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 Oraganization 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
4. Additional HPHC reports: [2]					
Cigarette Filler	78	2.56	200	1	200
Roll-Your-Own	39	5.12	200	1	200
Smokeless	52	3.84	200	1	200
Total					600
Total Section 904(c)(1) Reporting Burden Hours					4,447

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] HPHC reports for identical products (*e.g.,* under different brand or sub-brand names) in which the HPHC measures will be the same as the original report.

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 4,447 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.

As stated previously, FDA expects to receive 600 additional HPHC reports at 1 hour per response for a total of 600 hours. The estimated total annual burden for the reporting of HPHC under section 904(c)(1) of the FD&C Act is 4,447 hours.

Dated: March 2, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–05213 Filed 3–8–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0735]

Agency Information Collection Activities; Proposed Collection; Comment Request; Superimposed Text in Direct-to-Consumer Promotion of Prescription Drugs

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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on research entitled ''Superimposed Text in Direct-to-Consumer Promotion of Prescription Drugs.'' This study will examine how the size and presentation of superimposed text (supers) influences the comprehension of direct-to-consumer (DTC) television advertisements for prescription drugs.

DATES: Submit either electronic or written comments on the collection of information by May 9, 2016.

ADDRESSES: You may submit comments as follows: