4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0377]

Agency Information Collection Activities; Proposed Collection; Comment Request; Tobacco Health Document Submission

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 health documents that were created during the period of June 23, 2009, through December 31, 2009.

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: Submit electronic comments on the collection of information to http://www.regulations.gov. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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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.

Tobacco Health Document Submission--(OMB Control Number 0910-0654)--Extension

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111-31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding, among other things, a new 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 many new requirements for the tobacco industry. Section 101 of the Tobacco Control Act amended the FD&C Act by adding, among other things, section 904(a)(4) (21 U.S.C. 387d(a)(4)).

Section 904(a)(4) of the FD&C Act requires each tobacco product manufacturer or importer, or agent thereof, to submit all documents developed after June 22, 2009, "that relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives" (herein referred to as "tobacco health documents").

FDA announced the availability of a guidance on this collection in the Federal Register of April 20, 2010 (75 FR 20606), and requested tobacco health documents that were created during the period from June 23, 2009, through December 31, 2009. The guidance stated that information required under section 904(a)(4) must be submitted to FDA beginning December 22, 2009. Further, FDA stated it would publish a revised guidance specifying the timing of

subsequent reporting. FDA is in the process of revising the April 2010 guidance but will continue collecting documents created during the specified period for any manufacturers, importers, or their agents who still have documents to submit.

FDA has been collecting the information submitted pursuant to section 904(a)(4) through a facilitative electronic form and through a paper form (Form FDA 3743) for those individuals who choose not to use the electronic method. In both forms, FDA is requesting the following information from firms that have not already reported or still have documents to report:

- Submitter identification: Submitter type, company name, address, country, company headquarters Dun and Bradstreet number, and company headquarters Facility Establishment Identifier number;
- Submitter point of contact: Contact name, title, position title, email, telephone, and fax; and
- Submission format and contents (as applicable):
    - Electronic documents: Media type, media quantity, size of submission, quantity of documents, file type, and file software;
    - Paper documents: Quantity of documents, quantity of volumes, and quantity of boxes; and
    - Whether or not a submission is being provided.
- Confirmation statement (with identification and signature of submitter including name, company name, address, position title, email, telephone, and fax); and
- Document categorization (as applicable): Relationship of the document or set of documents to the following:
    - Health, behavioral, toxicological, or physiological effects;

- Specific current or future tobacco product(s);
- Class of current or future tobacco product(s);
- Specific ingredient(s), constituent(s), component(s), or additive(s);
- Class of ingredient(s), constituent(s), component(s), or additive(s).

● Document readability and accessibility: Keywords; glossary or explanation of any abbreviations, jargon, or internal (e.g., code) names; special instructions for loading or compiling submission; and

● Document metadata: Date document was created, document author(s), document recipient(s), document custodian, document title or identification number, beginning and ending Bates numbers, and Bates number ranges for documents attached to a submitted email.

In addition to the electronic and paper forms, the guidance that FDA issued in April 2010 (75 FR 20606) was intended to assist persons making tobacco health document submissions. For further assistance, FDA is providing a technical guide, embedded hints, and a Web tutorial on the electronic portal.

The estimated 50 hours per response burden is based on the average burden estimate among all 4 respondents. Therefore, on an individual basis, the actual burden per respondent may be higher or lower than the 50 hours estimate because it is an average value. FDA currently is evaluating the classification/coding recommendations and will revisit this issue in future guidance. The number of documents received each year since the original collection period has fallen to less than 5 percent of the number received in the original collection period. FDA expects this is because documents created within the specified period have already been submitted. Also, the number of respondents who still have documents to submit has decreased.

Therefore, FDA estimates the biannual burden of the continuation of this collection to be at most, 5 percent of the original burden.

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

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

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Tobacco Health Document Submissions and Form FDA 3743	4	2	8	50	400

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

Dated: April 4, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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