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

21 CFR Section and Part/Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
101.79(c)(2)(iv)	100	1	100	0.25	25
101.100(d)	1,000	1	1,000	1	1,000
101.105 and 101.100(h)	25,000	1.03	25,750	0.5	12,875
101.108	1	1	1	40	40
Total					1,109,873

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Record-keepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
101.12(e)	25	1	25	1	25
101.13(q)(5)	300,000	1.5	450,000	0.75	337,500
101.14(d)(2)	300,000	1.5	450,000	0.75	337,500
101.22(i)(4)	25	1	25	1	25
101.100(d)(2)	1,000	1	1,000	1	1,000
101.105(t)	100	1	100	1	100
Total					676,150

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

The estimated annual reporting and recordkeeping burdens are based on agency communications with industry and FDA's knowledge of and experience with food labeling and the submission of petitions and requests to the agency. Where an agency regulation implements an information collection requirement in the act or the FPLA, only any additional burden attributable to the regulation has been included in FDA's burden estimate.

No burden has been estimated for those requirements where the information to be disclosed is information that has been supplied by FDA. Also, no burden has been estimated for information that is disclosed to third parties as a usual and customary part of a food producer's normal business activities. Under 5 CFR 1320.3(c)(2), the public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public is not a collection of information. Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities.

In this request for extension of OMB approval under the PRA, FDA is no longer combining the burden hours associated with OMB Control Numbers 0910–0395 (collection titled, "Food Labeling: Nutrition Labeling of Dietary Supplements on a 'Per Day' Basis") and 0910–0515 (collection titled, "Food Labeling: Trans Fatty Acids in Nutrition Labeling"), with the burden hours approved under OMB Control Number 0910–0381 (collection titled, "Food Labeling Regulations") as announced previously. Such consolidation may occur in the future.

Dated: July 9, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–17229 Filed 7–14–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0185]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Tobacco Health Document Submission

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 (the PRA).

DATES: Fax written comments on the collection of information by August 16, 2010.

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 e-mailed to

oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910–0654. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3794, *Jonnalynn.Capezzuto@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.

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

On June 22, 2009, the President signed the Tobacco Control Act (Public Law 111–31) into law. The Tobacco Control Act granted FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. Among its many provisions, the Tobacco Control Act added section 904(a)(4) to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 387d(a)(4)), requiring submission of documents related to certain effects of tobacco products.

Section 904(a)(4) of the 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." Information required under section 904(a)(4) of the act must be submitted to FDA beginning December 22, 2009.

FDA issued a draft guidance document entitled "Tobacco Health Document Submission'" on December 28, 2009 (74 FR 68629) to assist persons making certain document submissions to FDA under section 904(a)(4) of the act. The guidance document was finalized on April 20, 2010 (75 FR 20606). While electronic submission of tobacco health documents is not required, FDA designed the eSubmitter application as an alternative for mailing documents. This electronic tool allows for importation of large quantities of structured data, attachments of files (e.g., in portable document format (PDFs) and certain media files), and automatic acknowledgement of FDA's receipt of submissions. FDA also developed a paper form (FDA Form 3743) as an alternative submission tool. Both the eSubmitter application and the paper form can be accessed at *http://www.fda.gov/tobacco*.

On September 1, 2009 (74 FR 45219), FDA published notice in the **Federal Register** announcing that a proposed collection of information had been submitted to OMB for emergency processing under the PRA. On September 15, 2009 (74 FR 47257), FDA published a notice correcting the length of the comment period, keeping it open until October 1, 2009. On October 13, 2009 (74 FR 52495), FDA published a notice reopening the comment period until October 26, 2009. On January 7, 2010, FDA received emergency approval for this information collection. Based on comments indicating that the burden estimate was too low, FDA has adjusted its original burden estimate from 1.0 hour per response to 200 hours per response. FDA also increased the annual frequency per response from 1 to 4 (quarterly).

FDA is maintaining the original estimate of the number of respondents at 10. FDA is basing its estimates on the total number of tobacco firms it is aware of, its experience with document production, and comments received in response to the draft guidance document published on December 28, 2009.

In the **Federal Register** of April 20, 2010 (75 FR 20603), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment in response to the 60-day notice soliciting public comment on the extension of OMB approval for this information collection. The comment stated that the classification/coding recommendations will impose burdens that significantly exceed the burden estimate of 200 hours and will likely inundate FDA with information with little incremental value. The estimated 200 hours per response burden is based on the average burden estimate among all 10 respondents. Therefore, on an individual basis, the actual burden per respondent may be higher or lower than the 200 hours estimate since it is an average value. FDA currently is evaluating the classification/coding recommendations and will revisit this issue in future guidance.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Tobacco Health Document Submission and Form FDA 3743	10	4	40	200	8,000

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

Dated: July 9, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–17230 Filed 7–14–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director; Notice of Establishment

Pursuant to the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), the Director, Office of Federal Advisory Committee Policy, National Institutes of Health (NIH), announces the establishment of the Interagency Pain Research Coordinating Committee.

Public Law 111–148 ("Patient Protection and Affordable Care Act"), Title IV, as it amends Part B of Title IV of the Public Health Service Act (42 USC 284 *et seq*.) requires the committee to: (a) Develop a summary of advances in pain care research supported or conducted by Federal agencies relevant to the diagnosis, prevention, and