Domestic Tobacco Product Establishments and Form FDA 3743—Listing of Ingredients in Tobacco Products) as an alternative submission tool. Both the eSubmitter application and the paper forms can be accessed at *http://www.fda.gov/tobacco.*

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

FDA form/ activity/TCA section	Number of respondents	Number of responses per respondent	Total annual responses	Hours per response	Total hours
Form FDA 3742 Registration and Product Listing for Owners and Operators of Domestic Establishments (Electronic and Paper submission) Sections 905(b), 905(c), 905(d) 905(h), or 905(i)	125	1.6	200	3.75	750
Form FDA 3743 Listing of Ingredients (Electronic and Paper Submissions) Sections 904(a)(1) or 904(c)	125	1.6	200	3.00	600
Obtaining a DUNS Number (10% of total respondents)	8	1	8	0.50	4
Total					1,354

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

Since this collection of information was last approved by OMB on December 2, 2010, its burden has decreased by 407,421 hours, from 408,775 to 1,354 reporting hours. This adjustment is a result of FDA experience over the past 2 years in the regulation of tobacco products and is based on the actual number of establishment registration and product ingredient submissions received during this time period. In 2010, when this collection was first published for public comment in the **Federal Register**, FDA attempted to determine the actual number of tobacco manufacturers by using the Security and Exchange Commission's Standard Industrial Classification (SIC) codes, which are identifying codes that appear in a company's EDGAR filings to show the company's type of business. When preparing the collection of information package for publication in 2010, the tobacco industry codes indicated that over 10,000 tobacco manufacturers existed under the SIC codes for tobacco products and cigarettes. However, upon further examination of these codes, it appears that the number of tobacco manufacturers was greatly inflated, as the SIC codes included tobacco retail in addition to tobacco manufacturers. In addition, no comments were received from the 2010 initial 60-Day **Federal Register** Notice regarding either the number of respondents or the number of reporting burden hours listed in the notice, so FDA used the collection's SIC-researched manufacturer numbers for this collection of information. Actual FDA registration and product listing report submissions and FDA experience indicate in the past 2 years, the number of tobacco manufacturers required to register and list their products and ingredient listings is approximately 125, a substantial decrease from the number of potential respondents listed in 2010. By applying the revised number of manufacturers to the burden chart, the total burden for registration and listing now is currently estimated to be 1,354 reporting burden hours, much less than the 408,775 OMB-approved reporting burden hours stated in 2010.

Based on the actual number of registration and product ingredient listing reports received by FDA over the past 2 years, the number of expected annual responses is projected to decrease from 100,000 registration responses to 200 annual responses, and from 11,000 annual product ingredient listing responses to 200 annual product ingredient responses. The Agency bases its estimate on the actual number of registration and listing and product ingredient listing reports received, its experience with the submission of registration and listing requirements applicable to other FDA regulated products, and ongoing interactions with industry. FDA estimates that the submission of registration information as required by section 905 of the FD&C Act will remain at 3.75 hours per establishment. Based on the actual number of registration information submitted over the past 2 years and its experience, the Agency estimates that approximately 200 registrations will be submitted from 125 tobacco product establishments annually, for a total 750 hour burden (125 respondents × 1.6 responses per respondent × 3.75 hours per response).

FDA estimates that the submission of ingredient listing information as required by section 904 of the FD&C Act will remain at 3.0 hours per tobacco product. Based on the actual number of product ingredient listings submitted over the past 2 years and its experience, the Agency estimates that approximately 200 ingredient listings will be submitted from 125 tobacco establishments, for a total 600 burden hours (125 respondents × 1.6 responses per respondent × 3.0 hours per response).

FDA estimates that obtaining a Dun and Bradstreet (DUNS) number will take 0.5 hours, and that 8 respondents (1 percent (1.25) of establishments required to register under section 905 and 5 percent (6.25) of submitters required to list ingredients under section 904) will not already have a DUNS number. The total burden, therefore, will be 4 hours (8 respondents × 1 response per respondent × 0.5 hours per response).

Total burden hours for this collection, therefore is 1,354 hours (750 + 600 + 4 hours).

Dated: April 26, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–10645 Filed 5–2–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0781]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Record Retention Requirements for the Soy Protein and Risk of Coronary Heart Disease Health Claim

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 June 4, 2012.

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 0910–0428. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400T, Rockville, MD 20850, 301–796–5733, *domini.bean@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.

Record Retention Requirements for the Soy Protein and Risk of Coronary Heart Disease Health Claim—21 CFR 101.82(c)(2)(ii)(B) (OMB Control Number 0910–0428)—Extension

Section 403(r)(3)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(r)(3)(A)) provides for the use of food label statements characterizing a relationship of any nutrient of the type required to be in the label or labeling of the food to a disease or a health-related condition only where that statement meets the requirements of the regulations promulgated by the Secretary of Health and Human Services to authorize the use of such a health claim. Section 101.82 (21 CFR 101.82) of FDA's regulations authorizes a health claim for food labels about soy protein and the risk of coronary heart disease (CHD). To bear the soy protein and CHD health claim, foods must contain at least 6.25 grams of soy protein per reference amount customarily consumed. Analytical methods for measuring total protein can be used to quantify the amount of soy protein in foods that contain soy as the sole source of protein. However, at the present time there is no validated analytical methodology available to quantify the amount of soy protein in foods that contain other sources of protein. For these latter foods, FDA must rely on information known only to the manufacturer to assess compliance with the requirement that the food contain the qualifying amount of soy protein. Thus, FDA requires manufacturers to have and keep records to substantiate the amount of soy protein in a food that bears the health claim and contains sources of protein other than soy, and to make such records available to appropriate regulatory officials upon written request. The information collected includes nutrient databases or analyses, recipes or formulations, purchase orders for ingredients, or any other information that reasonably substantiates the ratio of soy protein to total protein.

In the **Federal Register** of November 16, 2011 (76 FR 71040), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
101.82(c)(2)(ii)(B)	25	1	25	1	25

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

Based on the Agency's experience with the use of health claims, FDA estimates that only about 25 firms would be likely to market products bearing a soy protein/coronary heart disease health claim and that only, perhaps, one of each firm's products might contain non-soy sources of protein along with soy protein. The records required to be retained by § 101.82(c)(2)(ii)(B) are the records, e.g., the formulation or recipe, that a manufacturer has and maintains as a normal course of its doing business. Thus, the burden to the food manufacturer is limited to assembling and retaining the records, which FDA estimates will take 1 hour annually.

Dated: April 27, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–10647 Filed 5–2–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0867]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Review; Experimental Study on the Public Display of Lists of Harmful and Potentially Harmful Tobacco Constituents

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 June 7, 2012.

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–NEW and title ''Experimental Study on the Public Display of Lists of Harmful and Potentially Harmful Tobacco Constituents.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA