Improvement and Patient Safety, AHRQ, 540 Gaither Road, Rockville, MD 20850; Telephone (toll free): (866) 403–3697; Telephone (local): (301) 427–1111; TTY (toll free): (866) 438–7231; TTY (local): (301) 427–1130; Email: *pso@AHRQ.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Patient Safety Act, Public Law 109–41, 42 U.S.C. 299b–21—b–26, provides for the formation of PSOs, which collect, aggregate, and analyze confidential information regarding the quality and safety of health care delivery. The Patient Safety Rule, 42 CFR Part 3, authorizes AHRQ, on behalf of the Secretary of HHS, to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be ''delisted'' by the Secretary if it is found to no longer meet the requirements of the Patient Safety Act and Patient Safety Rule. Section 3.108(d) of the Patient Safety Rule requires AHRQ to provide public notice when it removes an organization from the list of federally approved PSOs, including when a PSO chooses to voluntarily relinquish its status as a PSO for any reason. Accordingly, CareRise LLC, PSO number P0058, was delisted effective at 12:00 Midnight ET (2400) on March 30, 2012.

More information on PSOs can be obtained through AHRQ's PSO Web site at *http://www.pso.AHRQ.gov/index.html.*

Dated: April 24, 2012.

Carolyn M. Clancy,

Director.

[FR Doc. 2012–10596 Filed 5–2–12; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

National Advisory Council for Healthcare Research and Quality: Request for Nominations for Public Members

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Notice of request for nominations for public members.

SUMMARY: 42 U.S.C. 299c establishes a National Advisory Council for Healthcare Research and Quality (the Council). The Council is to advise the Secretary of HHS (Secretary) and the Director of the Agency for Healthcare Research and Quality (AHRQ) on matters related to activities of the Agency to improve the quality, safety, efficiency, and effectiveness of health care for all Americans.

Seven current members' terms will expire in November 2012. To fill these positions, we are seeking individuals who are distinguished: (1) In the conduct of research, demonstration projects, and evaluations with respect to health care; (2) in the fields of health care quality research or health care improvement; (3) in the practice of medicine; (4) in other health professions; (5) in representing the private health care sector (including health plans, providers, and purchasers) or administrators of health care delivery systems; (6) in the fields of health care economics, information systems, law, ethics, business, or public policy; and, (7) in representing the interests of patients and consumers of health care. 42 U.S.C. 299c(c)(2). Individuals are particularly sought with experience and success in activities specified in the summary above.

DATES: Nominations should be received on or before 60 days after date of publication.

ADDRESSES: Nominations should be sent to Ms. Karen Brooks, AHRQ, 540 Gaither Road, Room 3006, Rockville, Maryland 20850. Nominations may also be emailed to *Karen.Brooks@ahrq.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Ms. Karen Brooks, AHRQ, at (301) 427–1801.

SUPPLEMENTARY INFORMATION: 42 U.S.C. 299c provides that the Secretary shall appoint to the National Advisory Council for Healthcare Research and Quality twenty one appropriately qualified individuals. At least seventeen members shall be representatives of the public and at least one member shall be a specialist in the rural aspects of one or more of the professions or fields listed in the above summary. In addition, the Secretary designates, as ex officio members, representatives from other Federal agencies, principally agencies that conduct or support health care research, as well as Federal officials the Secretary may consider appropriate. 42 U.S.C. 299c(c)(3). The Council meets in the Washington, DC, metropolitan area, generally in Rockville, Maryland, approximately three times a year to provide broad guidance to the Secretary and AHRQ's Director on the direction of and programs undertaken by AHRQ.

Seven individuals will be selected presently by the Secretary to serve on the Council beginning with the meeting in the spring of 2012. Members generally serve 3-year terms. Appointments are staggered to permit an orderly rotation of membership.

Interested persons may nominate one or more qualified persons for membership on the Council. Self-nominations are accepted. Nominations shall include: (1) A copy of the nominee's resume or curriculum vitae; and (2) a statement that the nominee is willing to serve as a member of the Council. Selected candidates will be asked to provide detailed information concerning their financial interests, consultant positions and research grants and contracts, to permit evaluation of possible sources of conflict of interest. Please note that once you are nominated, AHRQ may consider your nomination for future positions on the Council. Federally registered lobbyists are not permitted to serve on this advisory board pursuant to the Presidential Memorandum entitled ''Lobbyists on Agency Boards and Commissions'' dated June 10, 2010, and the Office of Management and Budget's ''Final Guidance on Appointment of Lobbyists to Federal Boards and Commissions,'' 76 FR 61756 (October 5, 2011).

The Department seeks a broad geographic representation. In addition, AHRQ conducts and supports research concerning priority populations, which include: Low-income groups; minority groups; women; children; the elderly; and individuals with special health care needs, including individuals with disabilities and individuals who need chronic care or end-of-life health care. See 42 U.S.C. 299(c). Nominations of persons with expertise in health care for these priority populations are encouraged.

Dated: April 24, 2012.

Carolyn M. Clancy,

Director.

[FR Doc. 2012–10595 Filed 5–2–12; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No.FDA–2012–N–0386]

Agency Information Collection Activities; Proposed Collection; Comment Request; Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments and Listing of Ingredients in Tobacco Products

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 proposed extension of an existing collection of information pertaining to registration and product listing for owners and operators of domestic tobacco product establishments and to listing of ingredients in tobacco products under the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act).

DATES: Submit either electronic or written comments on the collection of information by July 2, 2012.

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: 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: 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.

Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments and Listing of Ingredients in Tobacco Products (OMB Control Number 0910–0650)—Extension

On June 22, 2009, the President signed the Tobacco Control Act (Pub. L. 111–31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 301 *et seq.*) by, among other things, adding a new chapter granting the 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.

Section 905(b) of the FD&C Act (21 U.S.C. 395(b)), as amended by the Tobacco Control Act, requires that ''every person who owns or operates any establishment in any State engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products * * *'' register with the FDA the name, places of business, and all establishments owned operated by that person. Every person must register by December 31 of each year. Section 905(c) of the FD&C Act requires that first-time persons ''engaging in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products shall register with the Secretary the name, places of business, and all such establishments of that person.'' Section 905(d) states that persons required to register under sections 905(b) or 905(c) shall register any additional establishment that they own or operate in any state which begins the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products. Section 905(h) addresses foreign establishment registration requirements, which will go into effect when regulations are promulgated by the Secretary. Section 905(i)(1) of the FD&C Act, as amended by the Tobacco Control Act, requires that all registrants ''shall, at the time of registration under any such subsection, file with [FDA] a list of all tobacco products which are being manufactured, prepared, compounded, or processed by that person for commercial distribution,'' along with certain accompanying consumer information, such as all labeling and a representative sampling of advertisements. Section 904(a)(1) of the FD&C Act, as amended by the Tobacco Control Act, requires each tobacco product manufacturer or importer, or agent thereof, to submit ''a listing of all ingredients, including tobacco, substances, compounds, and additives that are * * * added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand or by quantity in each brand and subbrand.'' Since the Tobacco Control Act was enacted on June 22, 2009, the information required under section 904(a)(1) must be submitted to FDA by December 22, 2009, and include the ingredients added as of the date of submission. Section 904(c) of the FD&C Act also requires submission of information whenever additives, or the quantities of additives, are changed.

FDA issued guidance documents on both: (1) Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments (November 12, 2009, 74 FR 58298) and (2) Listing of Ingredients in Tobacco Products (December 1, 2009, 74 FR 62795) to assist persons making such submissions to FDA under the Tobacco Control Act. While electronic submission of registration and product listing information and ingredient listing information are not required, FDA is strongly encouraging electronic submission to facilitate efficiency and timeliness of data management and collection. To that end, FDA designed the eSubmitter application to streamline the data entry process for registration and product listing and for ingredient listing. This tool allows for importation of large quantities of structured data, attachment 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 paper forms (Form FDA 3742—Registration and Listing for Owners and Operators of

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]

BILLING CODE 4160–01–P

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.