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]

BILLING CODE 4160–01–P

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

has submitted the following proposed collection of information to OMB for review and clearance.

Experimental Study on the Public Display of Lists of Harmful and Potentially Harmful Tobacco Constituents—(OMB Control Number 0910–NEW)

The Tobacco Control Act (Pub. L. 111–31) amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to grant FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors. Section 904(d)(1) of the FD&C Act (21 U.S.C. 387d(d)(1)) states, ''Not later than 3 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, and annually thereafter, the Secretary shall publish in a format that is understandable and not misleading to a lay person, and place on public display (in a manner determined by the Secretary) the list [of harmful or potentially harmful constituents] established under [section 904(e)]'' of the FD&C Act. Section 904(e) of the FD&C Act (21 U.S.C. 387d(e)) directs FDA to establish ''a list of harmful and potentially harmful constituents, including smoke constituents, to health in each tobacco product by brand, and by quantity in each brand and subbrand.'' On January 31, 2011, FDA announced the availability of a final guidance representing the Agency's current thinking on the meaning of the term ''harmful and potentially harmful constituent'' (see 76 FR 5387, January 31, 2011). On April 3, 2012, FDA published a notice in the **Federal Register** establishing a list of the harmful and potentially harmful constituents (HPHCs) in tobacco products and tobacco smoke (see 77 FR 20034) as required by section 904(e) of the FD&C Act.

FDA intends to conduct research with consumers to help inform decisions about how to implement section 904(d)(1) of the FD&C Act and to provide information about how consumers understand information about HPHCs. The primary research goal is to evaluate the impact of different list formats on the public's ability to understand HPHC information. The impact of different list formats will be measured by evaluating respondents' understanding of certain communication objectives addressed in this document. Secondary outcomes of interest include measuring effects of different list formats upon respondents' susceptibility to initiation of tobacco use, motivation and confidence to quit tobacco use, and risk perceptions about tobacco use.

FDA proposes to conduct an experimental study with current smokers aged 13 years and older, smokeless tobacco users aged 18 years and older, and nonsmokers aged between 13 and 17 years who may be susceptible to initiation of smoking. Data will be collected from members of an Internet panel. Participation in the experimental study is voluntary. The information collected from the study is necessary to inform the Agency's efforts to implement the requirement of the FD&C Act to place on public display a list of HPHCs in tobacco products and tobacco smoke in a format that is understandable and not misleading to a lay person, and is expected to provide information that may inform Agency communications about HPHCs. The data obtained from this study is one factor that will be used to inform FDA's decisionmaking regarding the public display of the list of HPHCs required under section 904(d)(1). By evaluating respondents' understanding of the concepts listed in this document we do not intend to imply that consumer understanding of all concepts is needed to comply with these requirements.

In the **Federal Register** of December 14, 2011 (76 FR 77837), FDA published a 60-day notice requesting public comment on its proposed collection of information. FDA received eight comments that were PRA related, which required a total of 10 responses.

(Comment 1) One comment recommended that the study examine the effects of HPHC lists for smokeless tobacco products as well as for cigarettes.

(Response) FDA agrees. The proposed study will assess the impact of different HPHC list formats for three classes of tobacco products (cigarettes, smokeless tobacco products, and roll-your-own tobacco) on consumer comprehension, beliefs, perceptions, and other precursors to behavior.

(Comment 2) One comment encouraged FDA to recruit participants from multiple demographic groups.

(Response) FDA agrees that it is important to include a diverse group of individuals in the study and plans to include a demographically diverse sample of respondents drawn from four primary groups: Adult smoker, young adult smoker, youth smoker, and youth at risk for tobacco initiation.

(Comment 3) One comment recommended that FDA compare consumer responses to the HPHC lists against those that do not view an HPHC list. This would facilitate an evaluation of what consumers may understand, believe, perceive, or do in the absence of the HPHC list.

(Response) FDA agrees. Within each sample group, respondents will be randomly assigned to one of the treatment groups that view an HPHC list format or to a control group that does not view a list. Some of the formats will include additional information to provide context for the HPHC lists to the consumer. The effects of each list will be determined during analysis through a comparison of responses between treatment and control groups.

(Comment 4) One comment cautioned FDA to consider the utility of including underage nonsmokers in the experimental study.

(Response) FDA has considered the utility of including under age nonsmokers in the study. FDA believes it is important to consider the risks and benefits of the HPHC lists to the population as a whole, including users and nonusers of the tobacco product, and taking into account the increased or decreased likelihood that existing users of tobacco products will stop using such products, and the increased or decreased likelihood that those who do not use tobacco products will start using such products. Although FDA does not believe that there is any information on the HPHC list that would encourage nonusers to initiate tobacco use, one of the secondary outcomes it is to assess the effects of the provision of HPHC lists on youth that do not currently use tobacco products but who may be at risk of initiating the use of tobacco products.

(Comment 5) One comment recommended that the data collected from the users of smokeless tobacco products be analyzed separately from cigarette smokers.

(Response) FDA agrees. FDA will collect data on the use of tobacco products. The study now includes a sample of adult smokeless tobacco users aged 18 years and older. The data from those who use smokeless products will be analyzed separately.

(Comment 6) Three comments provided recommendations on pretesting the information provided in the lists with target audiences prior to implementation. One of these comments suggested that FDA use open-ended questions to allow respondents to say/type what they understand each statement to mean.

(Response) FDA agrees. FDA intends to conduct cognitive interviews with individuals to assess comprehension of the test instrument and certain aspects of the list formats prior to conducting the study. Individuals will be asked open-ended questions during the

cognitive testing of the list formats and the survey questions.

(Comment 7) Two comments encouraged FDA to provide additional information for public comment during the development of the study including the list formats, study design, and measurement plans for the listed unintended consequences.

(Response) The study protocol, list formats, and the survey questionnaire are available for review and public comment upon request. To request this information see the **FOR FURTHER INFORMATION CONTACT** section of this document.

(Comment 8) One commenter stated that the HPHC list could not fully inform consumers because the list is not complete, and the consumer would not understand that the listed quantity of the chemicals were based on machine testing and therefore are not necessarily a reflection of human use. Other comments argued there was a high likelihood that consumers will conclude that lower numbers or fewer constituents means a product is less risky. They also suggested the need to have disclaimers that provide information to counter potential misunderstandings.

(Response) FDA agrees that the list format may have the potential to mislead consumers, which is why FDA plans to conduct an experiment with consumers to assess the impact of various formats of the HPHC lists on consumer comprehension and precursors to behavior, such as beliefs, attitudes, and intentions. Some of the list formats to be included in the study will contain additional text and graphics to convey other information to consumers that may not be evident from a list of chemicals and numerical values. The study will assess various formats for conveying the communication goals enumerated in this document, such as uncertainty about the information contained in the list; that other relationships between the constituents in tobacco products and health problems may be discovered in the future; that the values are the results of machine testing; and that exposure to the chemicals also depends on other factors, such as the variability of human use.

FDA's proposed study will also assess each list's potential for increasing the likelihood that consumers will conclude that lower numbers or fewer constituents imply that a tobacco product is less risky. To evaluate whether the lists encourage consumers to compare the relative risks of products, the study will include measures, such as whether consumers comprehend that the amount of a chemical listed for a specific tobacco product does not necessarily indicate the likelihood of experiencing a health problem, and the number of chemicals listed for a specific tobacco product does not necessarily indicate the likelihood of experiencing a health problem.

(Comment 9) Two comments stressed the importance of using clear language with one suggesting that information be written at a fifth grade reading level. They also recommended FDA consider the impact of color, font type, and font size on consumer comprehension.

(Response) FDA intends to use plain language, where additional information is provided, and to select colors, font type, and font size that are likely to improve consumer comprehension.

(Comment 10) One commenter suggested FDA prioritize the communication objectives to facilitate evaluation of study results.

(Response) FDA agrees that a prioritization of the communication objectives may facilitate the evaluation of the results. At this time, FDA proposes a study to test the impact of various HPHC list formats on consumer comprehension of the communication objectives, although it is unlikely that a single format will be completely successful at meeting all of those objectives.

Based on comments received and preliminary qualitative research,[1] FDA has refined the communication objectives listed in the **Federal Register** of December 14, 2011 (76 FR 77837) to the following: (1) The chemicals come from the tobacco leaf itself and different parts of a tobacco product, such as the tobacco smoke, glues, inks, paper, and additives; (2) for smokeless products, many of the chemicals come from the tobacco leaf itself; for smoked products, many of the chemicals come from burning the tobacco leaf; (3) tobacco companies are required to test their tobacco products and smoke for the chemicals on the list and report the amounts to FDA; (4) science has linked the chemicals on these lists to health problems or potential health problems; (5) these lists do not necessarily identify all of the health problems that may be caused by the tobacco product; (6) these lists do not necessarily include all of the chemicals in the tobacco product that may be harmful; (7) the amount of a chemical listed for a specific tobacco product does not necessarily indicate the likelihood of experiencing a health problem; (8) the number of chemicals listed for a specific tobacco product does not necessarily indicate the likelihood of experiencing a health problem; and (9) when a chemical is listed without a quantity it may mean that the chemical was not detected or the information is not currently available.

The remaining comments were unresponsive to the 60-day **Federal Register** notice. These comments were related to the development of an accompanying education campaign; the development of a Web site for consumers to get additional information; the provision of HPHC information on the packages of tobacco products; the use of claims by tobacco manufacturers, such as ''all natural'' or ''no additives''; and the conformance of tobacco manufacturers and retailers to section 911 of the FD&C Act (21 U.S.C. 387k) regarding modified risk claims.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pretest	60	1	60	0.5	30
Screener	10,000	1	10,000	0.0167	167
Experimental Survey	3,150	1	3,150	0.5	1,575
Total					1,772

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

[1] OMB control number 0910–0674.

FDA's burden estimate is based on prior experience with Internet panel experiments similar to the study proposed here. Sixty panel members will take part in a pretest of the study, estimated to last 30 minutes (0.5 hours), for a total of 30 hours. Approximately 10,000 respondents will complete a screener to determine eligibility for participation in the study, estimated to take 1 minute (0.0167 hours), for a total of 167 hours. Three thousand one hundred and fifty respondents will complete the full study, estimated to last 30 minutes (0.5 hours), for a total of 1,575 hours. The total estimated burden is 1,772 hours.

Dated: April 27, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–10659 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–2012–N–0009]

Cooperative Agreement To Support the Joint Institute for Food Safety and Applied Nutrition, JIFSAN (U01)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of grant funds for the support of the Joint Institute for Food Safety and Applied Nutrition (JIFSAN). FDA believes that University of Maryland, College Park (UMCP)–JIFSAN is a sound investment to protect and promote public health. FDA faces an increasing number of critical and complex food safety and public health issues associated with the products that FDA regulates. These complex issues can be addressed most efficiently by expanding the scientific base through the development of collaborative partnerships. FDA believes that partnering with UMCP–JIFSAN will enhance FDA's ability to address safety and other public health issues related to foods, cosmetics, and animal health and continue to stimulate the integration of applied research, education, and outreach programs.

DATES: Important dates are as follows:

1. The application due date is June 1, 2012.

2. The anticipated start date is August 1, 2012.

3. The opening date is May 3, 2012.

4. The expiration date is June 2, 2012.

FOR FURTHER INFORMATION AND ADDITIONAL REQUIREMENTS CONTACT:

Elizabeth M. Calvey, Center for Food Safety and Applied Nutrition (HFS–560), Food and Drug Administration, CPK1, Rm. 4A007 (HFS–006), 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1981, *elizabeth.calvey@fda.hhs.gov.*

Gladys Melendez, Office of Acquisition & Grants Services (HFA–500), Food and Drug Administration, 5630 Fishers Lane, Rm. 1078, Rockville, MD 20857, 301–827–7175, *gladys.bohler@fda.hhs.gov.*

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA located at *http://www.fda.gov/food/newsevents/default.htm.*

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

Funding Opportunity Number: RFA–12–016.

Catalog of Federal Domestic Assistance Number: 93.103.

A. Background

FDA is announcing its intention to receive and consider a single source application for the award of a cooperative agreement in fiscal year 2012 (FY12) to UMCP to support JIFSAN.

FDA believes that the UMCP–JIFSAN collaboration is a sound investment. The last 15 years of FDA's partnership with UMCP–JIFSAN have been successful in developing multiple programs to support public health policy. The goal of JIFSAN is to advance sound strategies that improve public health, nutrition, and food/feed safety through three broad program areas: research, education, and outreach.

With an increasingly diverse domestic and global food supply, FDA continues to face complex food safety issues associated with products that it regulates (i.e., conventional foods; food ingredients; dietary supplements; cosmetics; animal feed, feed additives, and animal drugs). FDA believes that some of these complex issues can be effectively addressed by further strengthening the available science-based programs established through JIFSAN. FDA also believes that innovative capacity-building partnerships with various sectors of stakeholders in conjunction with JIFSAN's research and training programs can further support the development of proactive approaches to the prevention of problems before they occur. A proposal is being solicited for meeting this need as well as FDA's strategic goals to protect and promote public health.

B. Research Objectives

This cooperative agreement will provide continued support so that UMCP–JIFSAN can meet the following objectives:

- Establish multi-institutional, multidisciplinary applied research projects to address complex food/feed safety and public health issues associated with products that FDA regulates. Applied research includes not only traditional laboratory and field research, but also epidemiological, educational, social and behavioral science.
- Continue the development of mechanisms for the exchange of technical information and scientific concepts between FDA and other sectors of the international and domestic community, through workshops, short courses and symposia, and online resources that focus on existing and emerging complex food/feed safety and public health issues.
- Continue the development and refinement of programs based on the application of the principles of risk analysis to address food/feed defense and safety issues.
- Continue the design and improvement of domestic and international collaborations, which foster greater implementation of effective food safety practices.
- Continue developing innovative education and outreach programs that will provide opportunities to leverage resources among various sectors of stakeholders to address complex safety issues associated with an increasingly diverse global food supply.

C. Eligibility Information

Competition is limited to UMCP–JIFSAN because UMCP–JIFSAN is uniquely qualified to fulfill the objectives of the proposed cooperative agreement. The administrative structure and policies of UMCP–JIFSAN offer the flexibility needed to create and operate strategic alliances involving multiple partners. They also allow effective utilization of resources to plan and run multidisciplinary and multi-institutional research programs and internationally-recognized food safety training and risk analysis programs.

UMCP and FDA, through their collaboration in JIFSAN, developed FoodRisk.org, which is an extensive Web-based information resource addressing many aspects of food safety risk analysis, as well as providing tools