not necessarily indicate the likelihood of experiencing a health problem; (13) when a chemical is listed without a quantity it may mean that a manufacturer has not yet tested its products for that chemical; and/or that a test was conducted but it was not sensitive enough to measure the amount of chemical in the product; and/or that a way to test for that chemical is still being developed. Unintended consequences will be assessed by measuring respondents' susceptibility to initiation of tobacco use, motivation and confidence to quit tobacco use, risk perceptions about tobacco use, and emotional reactivity.

FDA proposes to conduct an experimental study with current smokers aged 15 years and older, former smokers aged 15 years and older, and nonsmokers aged between 13 and 25 years who may be susceptible to initiation of smoking. Data will be collected from members of an Internet panel. The study will include an oversampling of subjects with limited health literacy. 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 understood 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) of the FD&C Act. By evaluating respondents' understanding of the concepts listed previously in this document we do not intend to imply that consumer understanding of all concepts is needed to comply with these requirements.

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	3,000	1	3,000	0.5	1,500
Total	13,060				1,697

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

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 respondents will complete the full study, estimated to last 30 minutes (0.5 hours), for a total of 1,500 hours. The total estimated burden is 1,697 hours.

Dated: December 8, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–32026 Filed 12–13–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0535]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body

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 January 13, 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 0910–0374. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, (301) 796–3793.

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.

Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body—(OMB Control Number 0910–0374)—Extension

Section 403(r)(2)(G) and (r)(3)(C) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 343(r)(2)(G) and (r)(3)(C)), as amended by the FDA Modernization Act of 1997, provides that any person may market a food product whose label bears a nutrient content claim or a health claim that is based on an authoritative statement of a scientific body of the U.S. Government or the National Academy of Sciences (NAS). Under this section of

the FD&C Act, a person that intends to use such a claim must submit a notification of its intention to use the claim 120 days before it begins marketing the product bearing the claim. In the *Federal Register* of June 11, 1998 (63 FR 32102), FDA announced the availability of a guidance entitled ''Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body.'' The guidance provides the Agency's interpretation of terms central to the submission of a notification and the Agency's views on the information that should be included in the notification. The Agency believes that the guidance will enable persons to meet the criteria for notifications that are established in section 403(r)(2)(G) and (r)(3)(C) of the FD&C Act. In addition to the information specifically required by the FD&C Act to be in such notifications, the guidance states that the notifications should also contain information on analytical methodology for the nutrient that is the subject of a claim based on an authoritative statement. FDA intends to review the notifications the Agency receives to ensure that they comply with the criteria established by the FD&C Act.

In the *Federal Register* of August 3, 2011 (76 FR 46819), 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 REPORTING BURDEN [1]

Section of the FD&C Act	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
403(r)(2)(G) (nutrient content claims)	1	1	1	250	250
403(r)(2)(C) (health claims)	1	1	1	450	450
Guidance for notifications	2	1	2	1	2
Total					702

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

These estimates are based on FDA's experience with health claims, nutrient content claims, and other similar notification procedures that fall under our jurisdiction. To avoid estimating the number of respondents as zero, the Agency estimates that there will be one or fewer respondents annually for nutrient content claim and health claim notifications. FDA estimates that it will receive one nutrient content claim notification and one health claim notification per year over the next 3 years.

Section 403(r)(2)(G) and (r)(3)(C) of the FD&C Act requires that the notification include the exact words of the claim, a copy of the authoritative statement, a concise description of the basis upon which such person relied for determining that this is an authoritative statement as outlined in the FD&C Act, and a balanced representation of the scientific literature relating to the relationship between a nutrient and a disease or health-related condition to which a health claim refers or to the nutrient level to which the nutrient content claim refers. This balanced representation of the scientific literature is expected to include a bibliography of the scientific literature on the topic of the claim and a brief, balanced account or analysis of how this literature either supports or fails to support the authoritative statement.

Since the claims are based on authoritative statements of a scientific body of the U.S. Government or NAS, FDA believes that the information that is required by the FD&C Act to be submitted with a notification will be readily available to a respondent. However, the respondent will have to collect and assemble that information. Based on communications with firms that have submitted notifications, FDA estimates that 1 respondent will take 250 hours to collect and assemble the information required by the statute for a nutrient content claim notification. Further, FDA estimates that 1 respondent will take 450 hours to collect and assemble the information required by the statute for a health claim notification.

Under the guidance, notifications should also contain information on analytical methodology for the nutrient that is the subject of a claim based on an authoritative statement. The guidance applies to both nutrient content claim and health claim notifications. FDA has determined that this information should be readily available to a respondent and, thus, the Agency estimates that it will take a respondent 1 hour to incorporate the information into each notification. The Agency expects there will be 2 respondents for a total of 2 hours.

Dated: December 9, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–32025 Filed 12–13–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). To request a copy of the clearance requests submitted to OMB for review, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Cultural and Linguistic Competency and Health Literacy Data Collection Checklist (OMB No. 0915–xxxx)—[New].

The Health Resources and Services Administration's (HRSA) vision is ''Healthy Communities, Healthy People.'' In addition, the HRSA mission statement is ''To improve health and achieve health equity through access to quality services, a skilled health workforce and innovative programs.'' This framework supports a health care system that assures access to