marriage and responsible fatherhood grants and, where appropriate, administrators and managers of key partner agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
Discussion Guide	150	1	1	150

Estimated Total Annual Burden Hours: 150.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *OPREinfocollection@acf.hhs.gov*. In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above.

Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@acf.hhs.gov*. All requests should be identified by the title of the information collection.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: (202) 395–6974, Attn: Desk Officer for the Administration for Children and Families.

Dated: January 18, 2012.

Steven M. Hanmer,

Reports Clearance Officer, Office of Planning, Research and Evaluation.

[FR Doc. 2012–1569 Filed 1–26–12; 8:45 am]

BILLING CODE 4184–37–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0020]

Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study of Consumer Response to Health Claims and Disclaimers About the Relationship Between Selenium and Risk of Various Cancers

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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on a study entitled ''Experimental Study of Consumer Response to Health Claims and Disclaimers About the Relationship Between Selenium and Risk of Various Cancers.''

DATES: Submit either electronic or written comments on the collection of information by March 27, 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: Denver Presley II, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, (301) 796–3793.

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 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.

Experimental Study of Consumer Response to Health Claims and Disclaimers About the Relationship Between Selenium and Risk of Various Cancers—(OMB Control Number 0910—NEW)

I. Background

The Food and Drug Administration (FDA) regulates the labeling of food products under the Federal Food, Drug, and Cosmetic Act, as amended by the Nutrition Labeling and Education Act of 1990 (NLEA). NLEA regulations

establish general requirements for voluntary health claims in food labeling; health claims are labeling statements that characterize the relationship between a food substance and a disease or health-related condition (21 CFR 101.14(a)(1)). Under the petition process for new health claims (21 CFR 101.70), the petitioner must submit the scientific evidence supporting a proposed health claim to FDA for review. If FDA determines that there is significant scientific agreement (SSA) among experts that the proposed health claim is supported by the totality of publicly available evidence, FDA issues a regulation authorizing the claim (21 CFR 101.14(c)–(d)). Health claims must be ''complete, truthful, and not misleading'' (21 CFR 101.14(d)(2)(iii)) and must ''enable the public to comprehend the information provided and to understand the relative significance of such information in the context of a total daily diet'' (21 CFR 101.14(d)(2)(v)).

In a court challenge to FDA's decision not to authorize four dietary supplement health claims that failed to meet the SSA standard, the U.S. Court of Appeals for the D.C. Circuit held that the First Amendment does not permit FDA to prohibit health claims that the Agency determines to be potentially misleading unless the Agency also reasonably determines that a disclaimer would not eliminate the potential deception (*Pearson* v. *Shalala,* 164 F.3d 650 (D.C. Cir. 1999)). Because the court also held that a health claim is not inherently misleading simply because the evidence supporting it does not reach the SSA level, the decision effectively requires FDA to permit health claims that are backed by credible scientific evidence unless the Agency can demonstrate that the claim would mislead consumers. In response to the court's decision, FDA issued guidance on an interim review process for health claims that do not meet the SSA standard for the issuance of a regulation authorizing the claim (Ref. 1). These claims, referred to as ''qualified health claims'' (QHCs), include a disclaimer or other qualifying language to distinguish them from claims that meet the SSA standard and to prevent consumers from being misled about the level of scientific evidence supporting the claim (Ref. 2). When FDA reviews a QHC petition and determines that the proposed claim is supported by credible evidence and that it can be qualified to prevent consumers from being misled, the Agency issues a letter stating its intent to exercise enforcement discretion for the use of the QHC in food labeling.

In 2003, FDA issued a letter of enforcement discretion for two QHCs for dietary supplements containing selenium (Ref. 3):

Claim 1: ''Selenium may reduce the risk of certain cancers. Some scientific evidence suggests that consumption of selenium may reduce the risk of certain forms of cancer. However, FDA has determined that this evidence is limited and not conclusive.''

Claim 2: ''Selenium may produce anticarcinogenic effects in the body. Some scientific evidence suggests that consumption of selenium may produce anticarcinogenic effects in the body. However, FDA has determined that this evidence is limited and not conclusive.''

In 2007, FDA published a notice in the **Federal Register** (72 FR 72738; Dec. 21, 2007) announcing the Agency's intent to reevaluate these two QHCs, among other health claims (the 2007 notice). One of the other health claims being reevaluated is the authorized health claim for dietary fat and cancer risk in 21 CFR 101.73. The model health claims in § 101.73(e) use language similar to the ''certain cancers'' language used in Claim 1 for selenium, as they state that low-fat diets may reduce the risk of ''some cancers'' or ''some types of cancers.'' The 2007 notice explained that, during FDA's reevaluation of the scientific evidence underlying these claims, the Agency also planned to consider whether the claims should be revised to replace generic references to ''certain cancers'' (or similar language) with the names of specific cancers (*e.g.,* prostate cancer, breast cancer) because each type of cancer is a separate disease with different causes and risk factors (72 FR 72740).

In 2008, FDA received a petition requesting enforcement discretion for two additional QHCs similar to the ones for which FDA had issued a letter of enforcement discretion in 2003. The basic claim in the first sentence of each proposed QHC was the same as the claim in the first sentence of the corresponding 2003 QHC (''selenium may reduce the risk of certain cancers'' and ''selenium may produce anticarcinogenic effects in the body,'' respectively), but the 2008 petition requested enforcement discretion for the use of the following disclaimer with each claim: ''Scientific evidence supporting this claim is convincing but not yet conclusive.'' The 2008 petition also requested enforcement discretion for a number of other QHCs about selenium and reduced risk of specific cancers. In 2009, FDA issued a response to the 2008 petition in which the Agency stated its intent to exercise enforcement discretion for QHCs about selenium and reduced risk of prostate, thyroid, and bladder cancers (Ref. 4). The Agency declined to exercise enforcement discretion for QHCs about selenium and several other site-specific cancers because there was no credible evidence that selenium reduces the risk of those cancers. The Agency also declined to exercise enforcement discretion for the two QHCs that were similar to the 2003 ''certain cancers'' and ''anticarcinogenic effects'' QHCs because it concluded that the proposed claims were misleading and could not be cured with a disclaimer.

Several of the petitioners filed suit in the U.S. District Court for the District of Columbia, challenging FDA's 2009 petition response under the First Amendment. On cross-motions for summary judgment, the court ruled for the plaintiffs on the ''certain cancers'' and ''anticarcinogenic effects'' claims, as well as three of the site-specific cancer claims (*Alliance for Natural Health* v. *Sebelius,* 714 F. Supp. 2d 48 (D.D.C. 2010)). With respect to the ''certain cancers'' and ''anticarcinogenic effects'' QHCs, the court found that FDA had failed to show with empirical evidence that the claims were misleading and could not be corrected with disclaimers. The court also concluded that the Agency's scientific decisions regarding three QHCs for site-specific cancers were not supported by the record and remanded the case to FDA for reconsideration of those claims, along with the ''certain cancers'' and ''anticarcinogenic effects'' QHCs. FDA and the plaintiffs then reached a settlement whereby FDA agreed to exercise enforcement discretion for QHCs for selenium and reduced risk of bladder, prostate, colon, rectal, and thyroid cancers (Ref. 5). In lieu of the ''certain cancers'' and ''anticarcinogenic effects'' QHCs, plaintiffs agreed to accept a QHC that listed all five site-specific cancers.

II. Purpose and Methodology of Proposed Study

The objective of FDA's proposed study is to collect quantitative data to examine consumer interpretations of two dietary supplement labeling claims, ''selenium may reduce the risk of certain cancers'' and ''selenium may produce anticarcinogenic effects in the body,'' with and without various disclaimers. Previous studies conducted by FDA and others have examined consumer understanding of hypothetical QHCs and QHCs that are the subject of a letter of enforcement discretion. The primary goal of the previous studies was to evaluate ways to communicate the strength of scientific evidence

supporting a claim (Ref. 6 through 9). None of these studies, however, has investigated whether labeling claims using phrases such as ''certain cancers'' and ''anticarcinogenic effects'' may mislead consumers into having unjustified perceptions about the effects of a dietary supplement or food and how such misperceptions may affect behavioral intentions. The Agency therefore proposes to use selenium QHCs in this case study to examine consumer reactions to health claims using those phrases, with and without various disclaimers.

Specifically, the study plans to examine: (1) Whether one or both of the selenium claims quoted in this document would lead consumers to have the impression that selenium reduces the risk of all forms of cancer (''cancer in general''); (2) whether one or both of these claims would lead consumers to have the impression that selenium reduces the risk of a cancer for which there is no credible evidence of risk reduction, and, if so, whether a disclaimer specifying the names of the cancers for which there is such evidence (bladder, prostate, colon, rectal, and thyroid cancers) can communicate to consumers that the claimed risk reduction effect is only for the named cancers; (3) whether the ''anticarcinogenic effects'' claim would lead consumers to believe that selenium not only reduces the risk of cancer, but also treats or completely prevents cancer; (4) whether various disclaimer options for the two claims would correct potential consumer misperceptions about the nature of the relationship between selenium and various cancers or the scope of the claims; and (5) whether either of the claims leads consumers to have other erroneous perceptions, such as that all cancers are alike.

The proposed study will use a Web-based survey to collect information from approximately 1,200 adults, including 800 men who are 55 years or older and 400 women who are 50 years or older, who belong to online consumer panels maintained by a contractor. Data provided by the nationally representative Health Information National Trends Survey (HINTS; Ref. 10) suggest that individuals in the age groups proposed for this study have a higher overall prevalence of cancer in general, and a higher prevalence of most of the specific cancers that are the subject of an existing QHC for selenium (see list in I. Background section), but do not systematically differ from individuals in other age groups with respect to their patterns of cancer-related perceptions. By targeting participants in this age range and with these characteristics, the study is expected to maximize efficient use of the limited resources allocated to the project by yielding a greater amount of information pertinent to people who are more likely to take a selenium supplement. To that end, the study will aim for increased representation of potential selenium users by targeting a sample that includes at least 400 participants who have taken a selenium supplement at least once. Because the rate of selenium use in the general population is estimated to be low overall, but somewhat higher among men than women (Refs. 11 and 12), the sample will consist of a greater proportion of men. In addition, the screening process for the online consumer panel will limit female participants to those who report being married, and women enrolled in the study will be asked to provide information about their spouses' use of selenium in addition to their own.

On a computer screen, participants will view a label image and answer questions about their perceptions and behavioral intentions in response to the label they view. Each participant will be randomly assigned to an experimental condition in which he or she will view one of the following: (a) A selenium product label containing no claim; (b) a selenium product label containing the claim that ''selenium may reduce the risk of certain cancers''; (c) a selenium product label containing the claim that ''selenium may produce anticarcinogenic effects in the body''; (d) a selenium product label containing one of the claims from (b) or (c) plus a selected disclaimer statement. To help understand the data, the study will also collect information on each participant's background, including, but not limited to, health status, race/ethnicity, education, and income.

The proposed study is part of FDA's continuing effort to enable consumers to make informed dietary choices and eat healthful diets. Results of this case study will be used to further the Agency's understanding of how consumers may interpret ''certain cancers'' and ''anticarcinogenic effects,'' phrases that appear in a number of health claims that are authorized by regulation, as well as in some QHCs for which the Agency has issued a letter of enforcement discretion. Results of the study will not be used to develop population estimates.

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
Cognitive interview screener	72	1	72	0.083 hr. (5 minutes)	6
Cognitive interview	9	1	9	1 hr. (60 minutes)	9
Pretest invitation	240	1	240	0.033 hr. (2 minutes)	8
Pretest	60	1	60	0.167 hr. (10 minutes)	10
Survey invitation	50,000	1	50,000	0.033 hr. (2 minutes)	1,650
Survey	1,200	1	1,200	0.167 hr. (10 minutes)	200
Total					1,883

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

III. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. U.S. Food and Drug Administration, *Guidance for Industry: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Foods and Human Dietary Supplements,* 2003, available at *http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/*

FoodLabelingNutrition/ucm053832.htm.
2. U.S. Food and Drug Administration, *Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims,* 2009, available at *http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm073332.htm.*
3. U.S. Food and Drug Administration, ''Selenium and Certain Cancers (Qualified Health Claim: Final Decision Letter) (Docket No. 02P–0457),'' 2003, available at *http://www.fda.gov/Food/LabelingNutrition/LabelClaims/QualifiedHealthClaims/ucm072780.htm.*
4. U.S. Food and Drug Administration, ''Selenium and a Reduced Risk of Site-Specific Cancers (FDA–2008–Q–04323),'' 2009, available at *http://www.fda.gov/Food/LabelingNutrition/LabelClaims/QualifiedHealthClaims/ucm168527.htm.*
5. U.S. Food and Drug Administration, ''Settlement Reached for Qualified Health Claims Relating Selenium to Reduced Risk of Prostate, Colon, Rectal, Bladder, and Thyroid Cancers,'' 2011, available at *http://www.fda.gov/Food/LabelingNutrition/LabelClaims/QualifiedHealthClaims/ucm256940.htm.*
6. Derby, B.M. and A.S. Levy, *Effects of Strength of Science Disclaimers on the Communication Impacts of Health Claims,* 2005, available at *http://www.fda.gov/OHRMS/dockets/dockets/03N0496/03N–0496-rpt0001.pdf.*
7. Choinière, C. and L. Verrill, *Experimental Studies of Qualified Health Claims: Consumer Inferences about Monounsaturated Fatty Acids from Olive Oil, EPA and DHA Omega-3 Fatty Acids, and Green Tea,* 2009, available at *http://www.fda.gov/Food/LabelingNutrition/LabelClaims/QualifiedHealthClaims/ucm207549.htm.*
8. Hooker, N.H. and R. Teratanavat, ''Dissecting Qualified Health Claims: Evidence from Experimental Studies,'' *Critical Reviews in Food Science and Nutrition,* vol. 48, pp. 160–176, 2008.
9. Kapsak, W.R., D. Schmidt, N.M. Childs, *et al.,* ''Consumer Perceptions of Graded, Graphic and Text Label Presentations for Qualified Health Claims,'' *Critical Reviews in Food Science and Nutrition,* vol. 48, pp. 248–256, 2008.
10. National Cancer Institute, *Health Information National Trends Survey,* 2007, available at *http://hints.cancer.gov/.*
11. Bailey, R.L., J.J. Gahche, C.V. Lentino, *et al.,* ''Dietary Supplement Use in the United States, 2003–2006,'' *Journal of Nutrition,* vol. 141, pp. 261–266, 2011.
12. Radimer, K., B. Bindewald, J. Hughes, *et al.,* ''Dietary Supplement Use by US Adults: Data from the National Health and Nutrition Examination Survey, 1999–2000,'' *American Journal of Epidemiology,* vol. 160, pp. 339–349, 2004.

Dated: January 20, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–1692 Filed 1–26–12; 8:45 a.m.]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Recruitment of Sites for Assignment of National Health Service Corps Loan Repayors (FY 2012)

AGENCY: Health Resources and Services Administration, HHS.

ACTION: General notice.

SUMMARY: The Health Resources and Services Administration (HRSA) announces that the proposed list of the Health Professional Shortage Areas (HPSAs) and entities that would receive priority in applying for the assignment of National Health Service Corps (NHSC) Loan Repayors (Corps personnel, Corps members) during the period November 1, 2011, through September 30, 2012 is posted on the NHSC Web site at *http://datawarehouse.hrsa.gov/HGDWReports/OneClickRptFilter.aspx?rptName=NHSCAppSiteList&rptFormat=HTML3.2*. This database can be searched by State and will show the entities that have been approved by the NHSC for the assignment of NHSC Loan Repayment Program (LRP) participants serving as Corps members (*i.e.* Federal employees or Private Practice Assignees), as well as NHSC LRP participants wishing to exercise the Private Practice Option (PPO).

Eligible HPSAs and Entities

To be eligible to receive assignment of Corps personnel, entities must: (1) Have a current HPSA status of ''designated'' by the Office of Shortage Designation, Bureau of Health Professions, HRSA; (2) not deny requested health care services, or discriminate in the provision of services to an individual because the individual is unable to pay for the services or because payment for the services would be made under Medicare, Medicaid, or the Children's Health Insurance Program; (3) enter into an agreement with the State agency that administers Medicaid and the Children's Health Insurance Program, accept assignment under Medicare, and use and post a discounted fee plan (including fee waivers as appropriate); and (4) be determined by the Secretary to have (a) a need and demand for health manpower in the area; (b) appropriately and efficiently used Corps members assigned to the entity in the past; (c) general community support for the assignment of Corps members; (d) made unsuccessful efforts to recruit health care providers; (e) a reasonable prospect for sound fiscal management by the entity with respect to Corps members assigned there; and (f) demonstrated a willingness to support and facilitate mentorship, professional development and training opportunities for Corps members. Priority in approving applications for assignment of Corps members goes to sites that (1) provide primary medical care, mental health, or oral health services to a primary medical care, mental health, or dental HPSA of greatest shortage, respectively; (2) are part of a system of care that provides a continuum of services, including comprehensive primary health care and appropriate referrals or arrangements for secondary and tertiary care; (3) have a documented record of sound fiscal management; and (4) will experience a negative impact on its capacity to provide primary health services if a Corps member is not assigned to the entity. Sites that provide specialized care, or a limited set of services, will receive greater scrutiny and may not receive approval as NHSC service sites. This may include clinics that focus on one disease or disorder or offer limited services, such as a clinic that only provides immunizations or a substance abuse clinic. In order for a site to be eligible for placement of NHSC personnel, it must submit a Site Application and the Site Application must be approved by the NHSC. The NHSC site approval is good for a period of 3 years from the date of approval.

Entities that receive assignment of Corps personnel must ensure that (1) the position will permit the full scope of practice and that the clinician meets the credentialing requirements of the State and site; and (2) the Corps member assigned to the entity is engaged in the requisite amount of clinical service, as defined below, to meet his or her service obligation:

Full-Time Clinical Practice

''Full-time clinical practice'' is defined as a minimum of 40 hours per week for at least 45 weeks per service year. The 40 hours per week may be compressed into no less than 4 work days per week, with no more than 12 hours of work to be performed in any 24-hour period. Time spent on-call does not count toward the full-time service obligation, except to the extent the provider is directly serving patients during that period.

For all health professionals, except as noted below, at least 32 of the minimum 40 hours per week must be spent providing direct patient care or teaching in the outpatient ambulatory care setting(s) at the NHSC-approved service site(s) during normally scheduled office hours. The remaining 8 hours per week