

## B. Eligible Applicant

Assistance will be provided only to the Vietnam National Institute of Hygiene and Epidemiology through their Ministry of Health. Vietnam is being targeted for this cooperative agreement due to the recent outbreaks of highly pathogenic H5N1 avian influenza cases in humans and animals. The newly arising cases in humans are cause for great concern due to the potential of an influenza pandemic capable of causing millions of deaths. Since mid-December 2004, the Ministry of Health in Vietnam has confirmed 24 cases of human infection with H5N1 avian influenza. Of the 24 confirmed cases, 13 have resulted in fatalities. For the entire year of 2004, Vietnam had 28 human cases of H5N1 and 20 fatalities. Additionally, it appears that there are a growing number of possible family clusters suggesting the ability of the virus to spread through human to human contact. In response to these recent events in Vietnam, the Department of Health and Human Services requested that the Centers for Disease Control and Prevention create a cooperative agreement with Vietnam to enhance surveillance to address the current influenza situation as soon as possible. National Institute of Hygiene and Epidemiology (NIHE) has been chosen to conduct the surveillance for avian influenza because it serves as the National Influenza Center designated by the World Health Organization (WHO) and the Ministry of Health. As such, information collected by NIHE is reported directly into WHO's Global Influenza Surveillance System where it benefits countries globally.

## C. Funding

Approximately \$500,000 is available in FY 2005 to fund this award. It is expected that the award will begin on or before April 29, 2005 and will be made for a 12-month budget period within a project period of up to 5 years. Funding estimates may change.

## D. Where To Obtain Additional Information

For general comments or questions about this announcement, contact: Technical Information Management, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341-4146, Telephone: 770-488-2700.

For technical questions about this program, contact: Ann Moen, Project Officer, CDC, National Center for Infectious Diseases, Mailstop G-16, 1600 Clifton Road, NE., Atlanta, GA 30333, Telephone: 404-639-4652, E-mail: [AMoen@cdc.gov](mailto:AMoen@cdc.gov).

Dated: March 24, 2005.

**William P. Nichols,**

*Director, Procurement and Grants Office,  
Centers for Disease Control and Prevention.*  
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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2005N-0097]

#### **Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study of Qualified Health Claims: Consumer Inferences About Omega-3 Fatty Acids and Monounsaturated Fatty Acids From Olive Oil**

**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 voluntary experimental study of consumer inferences about qualified health claims for omega-3 fatty acids and monounsaturated fatty acids from olive oil.

**DATES:** Submit written or electronic comments on the collection of information by May 31, 2005.

**ADDRESSES:** Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. 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:** Peggy Robbins, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

**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 Qualified Health Claims: Consumer Inferences About Omega-3 Fatty Acids and Monounsaturated Fatty Acids From Olive Oil**

FDA regulates the labeling of food products under the Nutrition Labeling and Education Act of 1990 (NLEA) and dietary supplements under the Dietary Supplement Health and Education Act of 1994 (DSHEA). NLEA regulations establish general requirements for health claims in food labeling. A manufacturer is required to provide a description of the scientific evidence supporting a proposed health claim to FDA for review and authorization before the claim may appear in labeling. NLEA health claims must be "complete, truthful, and not misleading" (§101.14(d)(iii) (21 CFR 101.14 (d)(iii))). NLEA also mandates that "the claim enables the public to comprehend the information provided and to understand the relative significance of such information in the context of a total daily diet" (§101.14 (d)(v)).

In 2003, an FDA Task Force on Consumer Health Information for Better Nutrition issued a report that provided guidance on an interim review process

for health claims on food labels that do not meet a standard of significant scientific agreement (SSA). These claims, referred to as “qualified health claims,” are assigned a specific level of scientific support according to an interim evidence-based ranking system for scientific data. The report also identified the need for consumer research to examine ways to communicate the level of scientific support associated with health claims that do not meet the traditional SSA standard. In the fall of 2004, FDA issued letters of enforcement discretion for two qualified health claims. The claims relate to the reduction of risk of coronary heart disease from the consumption of monounsaturated fatty acids from olive oil and omega-3 fatty acids. The qualified health claims appear below:

1. Limited and not conclusive scientific evidence suggests that eating about 2 tablespoons (23 grams) of olive

oil daily may reduce the risk of coronary heart disease due to the monounsaturated fat in olive oil. To achieve this possible benefit, olive oil is to replace a similar amount of saturated fat and not increase the total number of calories you eat in a day. One serving of this product [Name of food] contains [x] grams of olive oil.

2. Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. One serving of [name of food] provides [x] grams of EPA and DHA omega-3 fatty acids. [See nutrition information for total fat, saturated fat and cholesterol content.]

The study proposed here is part of an ongoing effort by FDA to collect data concerning qualified health claims and their impact on consumer perceptions and behavior. Previous FDA studies have examined hypothetical qualified health claims to evaluate ways to

communicate the strength of scientific evidence supporting a claim. This study will examine two issued health claims to evaluate whether consumers comprehend the information contained within the claim and whether consumers understand the relative significance of the information in the context of a total diet. In addition, the study will broaden FDA’s understanding about how consumers interpret qualified health claims, particularly as they pertain to the level of scientific evidence conveyed by the message and to any differences there may be between qualified health claims on dietary supplements versus foods.

The experimental study data will be collected using participants of an Internet panel of approximately 600,000 people. Participation in the experimental study is voluntary.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
30 (Pre-test)	1	30	.167	5
1,600 (Experiment)	1	1,600	.167	267
Total				272

<sup>1</sup>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.

Dated: March 21, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Statement of Organization, Functions and Delegations of Authority**

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (DHHS), Health Resources and Services Administration (HRSA) (61 FR 65062–65065, December 10, 1996 and as last amended at 62 FR 27614–27615, dated May 20, 1997).

This notice is to amend the functions of a component of the Office of the Administrator. Specifically, this notice changes the name of the Office of

Minority Health to the Office of Minority Health and Health Disparities, and revises the functional statement as follows:

**Office of Minority Health and Health Disparities (RA9)**

Serves as the principal advisor and coordinator to the agency for the special needs of minority and disadvantaged populations including: (1) Providing leadership and direction to address HHS and HRSA Strategic Plan goals and objectives related to improving minority health and eliminating health disparities; (2) establishing and managing an agency-wide data collection system for minority health activities and initiatives including the White House Initiatives for Historically Black Colleges and Universities, Educational Excellence for Hispanic Americans, Tribal Colleges and Universities, Asian Americans and Pacific Islanders, and Departmental Initiatives; (3) implementing activities to increase the availability of data to monitor the impact of agency programs in improving minority health and eliminating health disparities; (4) participating in the formulation of HRSA’s goals, policies, legislative

proposals, priorities, and strategies as they affect health professional organizations and institutions of higher education and others involved in or concerned with the delivery of culturally-appropriate, quality health services to minorities and disadvantaged populations; (5) consulting with Federal agencies and other public and private sector agencies and organizations to collaborate in addressing minority health and health disparities issues, including enhancing cultural competence in health service providers; (6) establishing short-term and long-range objectives; and (7) participating in the focus of activities and objectives in assuring equity in access to resources and health careers for minorities and the disadvantaged.

**Section RA–30 Delegation of Authority**

All delegations of authority which were in effect immediately prior to the effective date hereof have been continued in effect in them or their successors pending further redelegation. I hereby ratify and affirm all actions taken by any DHHS official which involved the exercise of these