Therefore, FDA required that the terms ''some types of cancer'' or ''some cancers'' be used in specifying the disease for this health claim relationship (id.). The antioxidant and cancer and selenium and cancer qualified health claims also contain similar language, i.e., ''certain forms of cancer,'' to be used in specifying the disease. However, in other qualified health claims for a substance and cancer relationship (Refs. 6, 7, and 8), the agency considered separate qualified health claims for each type of cancer.

Cancer is a constellation of more than 100 different diseases, each characterized by the uncontrolled growth and spread of abnormal cells (Ref. 9). Cancer is categorized into different types of diseases based on the organ and tissue sites (Ref. 10). Cancers at different organ sites have different risk factors, treatment modalities, and mortality risk (Ref. 9). Both genetic and environmental (including diet) risk factors may affect the risk of different types of cancers. Risk factors may include a family history of a specific type of cancer, cigarette smoking, alcohol consumption, overweight and obesity, exposure to ultraviolet or ionizing radiation, exposure to cancer-causing chemicals, and dietary factors. The etiology, risk factors, diagnosis, and treatment for each type of cancer are unique (Refs. 11 and 12). Because each form of cancer is a unique disease based on organ site, risk factors, treatment options, and mortality risk, FDA's current approach is to evaluate each form of cancer individually in a health claim or qualified health claim petition to determine whether the scientific evidence supports the potential substance-disease relationship for any type of cancer, each of which constitutes a disease under § 101.14(a)(5).

The agency intends to consider, as part of its reevaluation of the scientific evidence for dietary fat, antioxidant, and selenium and their association with a reduced risk of cancer, claim language to reflect specific types of cancer rather than ''certain forms of cancer'' (or similar language).

II. How to Submit Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individual may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that in January 2008, the FDA Web site is expected to transition to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. After the transition date, electronic submissions will be accepted by FDA through the FDMS only. When the exact date of the transition to FDMS is known, FDA will publish a **Federal Register** notice announcing that date.

III. References

The following references have been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 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 subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. Balk E, Chung M, Chew P, Ip S, Raman G, Kupelnick B, Tatsioni A, Sun Y, Wolk B, DeVine D, Lau J. Effects of Soy on Health Outcomes. Summary, Evidence Report/ Technology Assessment No. 126. (Prepared by the Tufts-New England Medical Center Evidence-based Practice Center under Contract No. 290–02–0022.) AHRQ Publication No. 05–E024–1. Rockville, MD: Agency for Healthcare Research and Quality. July 2005.

2. Institute of Medicine, National Academy of Sciences. *Dietary Referece Intakes for energy, carbohydrate, fiber, fat, fatty acids, cholesterol, protein and amino acids, Chapter 11 page 808*. National Academy Press. Washington, D.C. 2005.

3. Antioxidant vitamins and risk of certain cancers, April 1, 2003, *http://www.cfsan.fda.gov/~dms/ds-ltr34.html*.

4. Selenium and certain cancers, February 21, 2003, Docket No. 2002P–0457 (formerly Docket No. 02P–0457), *http://www.cfsan.fda.gov/~dms/ds-ltr35.html*.

5. Huang HY, Caballero B, Chang S, Alberg A, Semba R, Schneyer C, Wilson RF, Cheng TY, Prokopowicz G, Barnes II GJ, Vassy J, Bass EB. Multivitamin/Mineral Supplements and Prevention of Chronic Disease. Evidence Report/Technology Assessment No. 139. (Prepared by The Johns Hopkins University Evidence-based Practice Center under Contract No. 290–02–0018). AHRQ Publication No. 06–E012. Rockville, MD: Agency for Healthcare Research and Quality. May 2006.

6. Tomatoes and prostate, ovarian, gastric and pancreatic cancers, November 8, 2005, Docket No. 2004Q–0201, *http://www.cfsan.fda.gov/~dms/qhclyco.html*.

7. Green tea and prostate and breast cancer risk, June 30, 2005, Docket No. 2004Q–0083, *http://www.cfsan.fda.gov/~dms/qhc-gtea.html*.

8. Calcium and colon/rectal, breast and prostate cancers and recurrent polyps, October 12, 2005, Docket No. 2004Q–0097, *http://www.cfsan.fda.gov/~dms/qhcca2.html*.

9. American Cancer Society, Cancer Facts and Figures, 2004.

10. National Cancer Institute, Dictionary of Cancer Terms, *http://www.cancer.gov/Templates/db_alpha.aspx?CdrID=45333*.

11. Hord NG, Fenton JI. Context is everything: mining the normal and preneoplastic microenvironment for insights into the diet and cancer risk conundrum. *Molecular Nutrition and Food Research*, 2007, 51:100–106.

12. Milner JA. Diet and Cancer: Facts and Controversies. *Nutrition and Cancer*, 2006, 56:216–224.

Dated: December 6, 2007.

Barbara Schneeman,

Director, Office of Nutritional Products, Labeling, and Dietary Supplements, Center for Food Safety and Applied Nutrition.

[FR Doc. E7–24813 Filed 12–20–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Announcement of Potential Eligibility for Compensation Under Public Readiness and Emergency Preparedness Act Declaration and Filing Deadlines

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notice.

SUMMARY: This Notice provides notification that individuals who have been injured by pandemic, epidemic, or security countermeasures identified in a declaration issued by the Secretary pursuant to section 319F–3(b) of the Public Health Service Act (PHS Act) (42 U.S.C. 247d–6d) have one (1) year from the time they receive the covered countermeasure to file requests for compensation for injuries directly resulting from administration or use of covered countermeasures under the Public Readiness and Emergency Preparedness Act (PREP Act).

DATES: This Notice is effective on December 21, 2007.

FOR FURTHER INFORMATION CONTACT: Healthcare Systems Bureau, Health Resources and Services Administration, Parklawn Building, Room 11C–26, 5600 Fishers Lane, Rockville, Maryland 20857; toll-free telephone number 1–888–496–0338. Electronic inquiries should be sent via Tamara Overby at *toverby@hrsa.gov*.

SUPPLEMENTARY INFORMATION: The PREP Act, which is a part of the ''Department of Defense, Emergency Supplemental Appropriations to Address Hurricanes in the Gulf of Mexico, and Pandemic Influenza Act of 2006'' (Pub. L. 109–148), was enacted on December 30, 2005, and confers broad liability protections on covered persons, as defined in section 319F–3(i)(2) of the PHS Act, and compensation to individuals injured by the receipt of covered countermeasures, as defined in section 319F–3(i)(1) of the PHS Act, in the event of designated public health emergencies. A covered countermeasure means: (A) A qualified pandemic or epidemic product (as defined in section 319F–3(i)(7) of the PHS Act); (B) a security countermeasure (as defined in section 319F–2(c)(1)(B) of the PHS Act); or (C) a drug (as such term is defined in section 201(g)(1) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(g)(1)), biological product (as such term is defined by section 351(i) of this Act), or device (as such term is defined by section 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(h)) that is authorized for emergency use in accordance with section 564 of the Federal Food, Drug and Cosmetic Act.

Passed primarily to address the pandemic influenza threat, the PREP Act provides liability protections after a Secretarial declaration of covered countermeasures for any disease or health condition that the Secretary views as constituting a public health emergency, either presently or in the future. Liability protections cover the manufacture, testing, development, distribution, or use of the designated covered countermeasure absent willful misconduct as defined in section 319F–3(c)(1) of the PHS Act. A Secretarial declaration specifies the categories of health threats or conditions for which countermeasures are recommended, the period liability protections are in effect, the population of individuals protected, and the geographic areas for which the protections are in effect.

In addition to liability protections, the PREP Act provides the Secretary the authority, which was delegated by the Secretary on November 8, 2006 to the Administrator of the Health Resources and Services Administration, to compensate eligible individuals for covered injuries from a covered countermeasure.

The first Declaration under the PREP Act was published in the **Federal Register** on February 1, 2007 (72 FR 4710). It designated the pandemic influenza A (H5N1) vaccine as a covered countermeasure, with an effective time period of December 1, 2006–February 28, 2010. As a result of this Declaration, individuals injured by this vaccine can file a request for compensation. Individuals have one (1) year from the time they receive the vaccine to apply for compensation. Currently, no funds have been appropriated to provide compensation. However, all potential claims must still be filed within the one (1) year limit.

This Declaration specifies that the following individuals with covered injuries may be eligible to receive compensation under the PREP Act: (1) All persons who use a covered countermeasure or to whom such a covered countermeasure is administered as an Investigational New Drug in a human clinical trial conducted directly by the Federal Government, or pursuant to a contract, grant or cooperative agreement with the Federal Government; (2) all persons who use a covered countermeasure or to whom such a countermeasure is administered in a pre-pandemic phase; and/or (3) all persons who use a covered countermeasure, or to whom such a covered countermeasure is administered in a pandemic phase. The Pre-Pandemic Phase means the following stages, as defined in the National Strategy for Pandemic Influenza: Implementation Plan (Homeland Security Council, May 2006): (0) New Domestic Animal Outbreak in At-Risk Country; (1) Suspected Human Outbreak Overseas; (2) Confirmed Human Outbreak Overseas; and (3) Widespread Human Outbreaks in Multiple Locations Overseas. The Pandemic Phase means the following stages, as defined in the National Strategy for Pandemic Influenza: Implementation Plan (Homeland Security Council, May 2006): (4) First Human Case in North America; and (5) Spread Throughout United States.

Eligible individuals may be compensated for out-of-pocket medical expenses, lost employment income, and survivor death benefits. Reasonable and necessary medical items and services may be paid or reimbursed to treat a covered countermeasure-related injury of an eligible individual. The payments or reimbursements for services or benefits are secondary to other forms of coverage. The individual may receive compensation for loss of employment income incurred as a result of the covered countermeasure injury. The amount of compensation is based on income at the time of injury. Death benefits may be paid to certain survivors of covered countermeasures recipients who have died as a direct result of the covered countermeasure injury. Since HHS is payer of last resort, payments are reduced by those of other third party payers.

Interested parties may obtain request packages that contain copies of all necessary forms and instructions by writing to the Healthcare Systems Bureau, Health Resources and Services Administration, Parklawn Building, Room 11C–26, 5600 Fishers Lane, Rockville, MD 20857, calling at 1–888–496–0338, or downloading them from the HRSA Web site at *http://www.hrsa.gov/countermeasurescomp.*

Completed request packages must be postmarked by the U.S. Postal Service, a commercial carrier, or a private courier service. HRSA will not accept request packages electronically or by hand-delivery. The postmark date is used to determine whether the filing deadline of one year from receipt of the countermeasure has been met.

Paperwork Reduction Act of 1995

HRSA will submit to the Office of Management and Budget (OMB) an Information Collection Request (ICR) for approval of the required forms.

Dated: December 18, 2007.

Elizabeth M. Duke,

Administrator.

[FR Doc. 07–6180 Filed 12–19–07; 1:36 pm]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Cancer Care for Uninsured Individuals: A Feasibility Study (NCI)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI) of the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: Cancer Care For Uninsured Individuals: A Feasibility Study. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* The purpose of this information collection is to conduct a pilot study to assess the feasibility of obtaining health insurance information for participants of the Prostate, Lung, Colon and Ovarian (PLCO) Cancer Screening Trial participants from health