through implicit deduction based on small cell sizes (instances where the patient population is so small that individuals who are familiar with the enrollees could, because of the small size, use this information to deduce the identity of the individual).

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

All records are stored electronically and in hard copy.

RETRIEVABILITY:

The complaint data are retrieved by an individual identifier i.e., name of complainant.

SAFEGUARDS:

CMS has safeguards in place for authorized users and monitors such users to ensure against excessive or unauthorized use. Personnel having access to the system have been trained in the Privacy Act and information security requirements. Employees who maintain records in this system are instructed not to release data until the intended recipient agrees to implement appropriate management, operational and technical safeguards sufficient to protect the confidentiality, integrity and availability of the information and information systems and to prevent unauthorized access.

This system will conform to all applicable Federal laws and regulations and Federal, HHS, and CMS policies and standards as they relate to information security and data privacy. These laws and regulations may apply but are not limited to: The Privacy Act of 1974; the Federal Information Security Management Act of 2002; the Computer Fraud and Abuse Act of 1986; the Health Insurance Portability and Accountability Act of 1996; the E-Government Act of 2002, the Clinger-Cohen Act of 1996; the Medicare Modernization Act of 2003, and the corresponding implementing regulations. OMB Circular A–130, Management of Federal Resources, Appendix III, Security of Federal Automated Information Resources also applies. Federal, HHS, and CMS policies and standards include but are not limited to: all pertinent National Institute of Standards and Technology publications; the HHS Information Systems Program Handbook and the CMS Information Security Handbook.

RETENTION AND DISPOSAL:

CMS will retain complaint information for a total period not to exceed 25 years.

SYSTEM MANAGER AND ADDRESS:

Director, Division of Continuing Care Providers, Survey and Certification Group, Center for Medicaid and State Operations, CMS, 7500 Security Boulevard, Mail Stop S2–01–16, Baltimore, Maryland 21244–1849.

NOTIFICATION PROCEDURE:

This system is exempt under the provisions of 5 U.S.C. 552a(k)(2) of the Privacy Act. However, portions of this system notice are non-exempt and consideration will be given to requests addressed to the system manager for those portions. For general inquiries, it would be helpful if the request included the system name, address, age, sex, and for verification purposes, the subject individual's name (woman's maiden name, if applicable) and complaint tracking identification number.

RECORD ACCESS PROCEDURE:

For purpose of access, use the same procedures outlined in Notification Procedures above. Requestors should also reasonably specify the record contents being sought. (These procedures are in accordance with Department regulation 45 CFR 5b.5(a)(2).)

CONTESTING RECORDS PROCEDURES:

The subject individual should contact the system manager named above and reasonably identify the records and specify the information to be contested. State the corrective action sought and the reasons for the correction with supporting justification. (These Procedures are in accordance with Department regulation 45 CFR 5b.7).

RECORDS SOURCE CATEGORIES:

CMS investigative files maintained in OPOS are either received as electronic documents or paper records that are compiled for administrative, civil, and law enforcement purposes. In the course of investigations, CMS often has a need to obtain confidential information involving individuals other than the complainant.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

HHS claims exemption of certain records (case files on active fraud investigations) in the system from notification and access procedures under 5 U.S.C. 552a(k)(2) inasmuch as these records are investigatory materials compiled for program, administrative, and law enforcement in anticipation of a criminal or administrative proceedings. (See Department Regulation (45 CFR 5b.11)).

[FR Doc. E6–7690 Filed 5–19–06; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0097]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Experimental Study of Qualified Health Claims: Consumer Inferences About Omega-3 Fatty Acids, Monounsaturated Fatty Acids From Olive Oil, and Green Tea

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 21, 2006.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. 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: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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 of Qualified Health Claims: Consumer Inferences About Omega-3 Fatty Acids, Monounsaturated Fatty Acids From Olive Oil, and Green Tea

FDA regulates health claims in the labeling of food products under the Nutrition Labeling and Education Act of 1990 (NLEA). 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 before the claim may appear in labeling (§§ 101.14(c) and (d),

101.70 (21 CFR 101.14(c) and (d), 101.70)). If FDA determines that there is significant scientific agreement among experts that the proposed health claim is supported by the totality of publicly available evidence, FDA issues a regulation authorizing the claim. Health claims must be ''complete, truthful, and not misleading'' (§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'' (§ 101.14 (d)(2)(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 that do not meet the significant scientific agreement (SSA) standard for the issuance of a regulation authorizing the claim. These claims, referred to as ''qualified health claims,'' are evaluated according to an interim evidence-based ranking system for scientific data and include a disclaimer or other qualifying language to distinguish them from claims that meet the SSA standard. The report also identified the need for consumer research to examine ways to communicate the level of scientific support associated with qualified health claims.

In the fall of 2004, FDA issued letters of enforcement discretion for two qualified health claims about the relationship between risk of coronary heart disease and consumption of monounsaturated fatty acids from olive oil and omega-3 fatty acids, respectively. 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.]

In June 2005, FDA issued a letter of enforcement discretion for two qualified health claims about the relationship between risk of breast and prostate cancers and consumption of green tea. The qualified claims appear below:

1. Two studies do not show that drinking green tea reduces the risk of breast cancer in women, but one weaker, more limited study suggests that drinking green tea may reduce this risk. Based on these studies, FDA concludes that it is highly unlikely that green tea reduces the risk of breast cancer.

2. One weak and limited study does not show that drinking green tea reduces the risk of prostate cancer, but another weak and limited study suggests that drinking green tea may reduce this risk. Based on the studies, FDA concludes that it is highly unlikely that green tea reduces the risk of prostate cancer.

In November 2005, FDA released the results of a prior study of qualified health claims to assess the effectiveness of claim language and grading schemes for conveying the level of scientific evidence supporting the claim. The study showed that report card schemes helped consumers distinguish between various levels of scientific support. However, the report card scheme inadvertently conveyed other nutrient and product attributes to consumers. In particular, report card schemes resulted in ''halo effects'' and other misperceptions concerning the general healthfulness and quality of the product. In addition, the study showed that consumers attributed higher levels of scientific support to certain qualified health claims bearing a grade of ''B'' than to non-graded claims that meet FDA's standard of ''SSA''. Thus, the study proposed here will further explore the report card grading scheme by modifying it in two ways. First, the study will test the ability of grade disclaimers to correct for some of the misperceptions created by report card schemes observed in the earlier study. Second, the study will include SSA claims as ''A'' grade claims within the report card grade scheme.

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 four qualified health claims and two SSA claims to evaluate whether consumers comprehend the information in 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. Participation in the experimental study is voluntary.

In the **Federal Register** of March 30, 2005 (70 FR 16291), FDA published a 60-day notice requesting public comment on the information collection provisions. At that time, the experimental study was titled ''Experimental Study of Qualified Health Claims: Consumer Inferences about Omega-3 Fatty Acids and Monounsaturated Fatty Acids from Olive Oil.'' Previously, it did not include the two qualified health claims for green tea or the two SSA health claims, and the study also did not include further exploration of the report card grading scheme for health claims. The study is now renamed to indicate the inclusion of the green tea claims. Burden estimates have also been adjusted to account for the increase in respondents necessary to make these changes in the study.

FDA received four letters in response to the notice, each containing one or more comments. One of the letters and portions of another letter contained comments that were not responsive to the four PRA questions for which comments were requested. One of these comments was about the presence of monounsaturated fatty acids in oils other than olive oil, while the others raised legal issues outside the scope of the PRA. These comments will not be addressed in this document, which is intended to summarize and respond to comments about PRA issues. The comments that addressed the four PRA questions and our responses follow.

One comment expressed concern that the proposed collection of information is unnecessary for the proper performance of the agency's functions and that the information will have no practical utility. The comment asserted that the information to be collected will be inadequate for the agency to assess whether consumer confusion will arise from the claims.

FDA disagrees. The study is part of an ongoing effort by FDA to collect data concerning the communications effects of qualified health claims on consumer perceptions and judgments. The purpose of the study is to assess how some claim language compares to other claim language in conveying information to consumers. The study

uses an experimental design to assess consumer reactions to health claim language intended to convey both the potential health benefits and the level of scientific support for the health claim.

The comment also suggested that the information will not be useful if it is the agency's intent to alter or restrict the wording of qualified health claims because, according to the comment, consumers have the right to receive truthful information, regardless of whether they understand that information.

FDA disagrees. The agency has a responsibility to ensure that disclaimers and other qualifying language intended to prevent consumer deception are effective in serving that purpose. The study is designed to evaluate whether certain variants of the qualified health claims are more effective than others at conveying to consumers the potential health benefits and the level of scientific support for the health claim. FDA expects this study to be useful in determining language that effectively conveys this information to consumers.

The comment suggested that there might be ways to improve the quality or utility of the information collection, yet did not offer specific recommendations to modify the study and analysis. In particular, the comment expressed concern that an Internet survey cannot be used to measure consumer confusion.

FDA responds that the experimental study that is the basis of this information collection request is an Internet-based experiment, not an Internet survey. The experimental study is intended to assess the communication effects, in a large sample of study participants, of both existing health claim language that appears on dietary supplements and conventional food products and variants of such language. The study is not intended to measure consumer confusion per se.

One comment recommended that, to help maximize the quality, utility and accuracy of the data to be collected in the study, FDA should test the qualified claim language exactly as stated in the **Federal Register** notice published March 30, 2005.

FDA agrees. The experimental study will test the qualified claim language exactly as it appears in the notice, in addition to variants of the claim language.

A comment urged FDA to takes steps to ensure that using electronic data collection is reliable and verifiable for the study.

FDA is confident that the methodology is reliable and verifiable for this type of study. FDA will closely monitor the contractor that implements the experiment to ensure the validity and accuracy of the collected data.

Another comment supported FDA's efforts to understand consumer responses to food and dietary supplement labels, but expressed concern that FDA has not supplied sufficient information to evaluate whether the estimated burden of the proposed collection is accurate.

FDA believes that the estimate of burden is accurate because the estimate is based on past experience with Internet panel experiments similar in complexity and duration to the one proposed here. The study protocol will be available for public viewing when this 30-day notice is published. FDA has followed the procedures for public notice and comment about this information collection set out in the PRA (44 U.S.C. 3501–3520) and OMB regulations (5 CFR part 1320).

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
30 (pre-test)	1	30	.16	5
7,440 (experiment)	1	7,440	.16	1,191
TOTAL				1,196

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

Dated: May 12, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–7692 Filed 5–19–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0443]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Focus Groups as Used by the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Focus Groups as Used by the Food and Drug Administration'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 27, 2006 (71 FR 9828), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0497. The approval expires on November 30, 2007. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: May 12, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–7698 Filed 5–19–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0183]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance on Reagents for Detection of Specific Novel Influenza A Viruses

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.