in households at high risk for fire and fire-related injury and death. Programs of this type are thought to prevent fire-related injury and mortality, but have not been studied scientifically to assess their impact on fire-related injury outcomes. The proposed study represents the first formal effort to evaluate the effectiveness and cost implications of the SAIFE program as implemented in North Carolina. The data collected in this study will have the potential to impact other smoke alarm installation programs, as well as indicate future priorities in prevention and preparedness for residential fires. There are no costs to the respondents other than their time. The total estimated annualized burden hours are 251.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	No. of respondents	No. of responses per respondent	Average burden per response (in hours).
Adult male and female (age 18+ years) screened	425	1	5/60
Adult male and female (age 18+ years) Pre/Post Evaluation survey	360	2	15/60
Adult male and female (age 18+ years) household visit	36	1	1

Dated: May 8, 2006.

Joan F. Karr,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E6–7732 Filed 5–19–06; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Decision To Evaluate a Petition To Designate a Class of Employees at Monsanto Chemical Company, Dayton, Ohio, To Be included in the Special Exposure Cohort

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) gives notice as required by 42 CFR 83.12(e) of a decision to evaluate a petition to designate a class of employees at Monsanto Chemical Company, Dayton, Ohio, to be included in the Special Exposure Cohort under the Energy Employees Occupational Illness Compensation Program Act of 2000. The initial proposed definition for the class being evaluated, subject to revision as warranted by the evaluation, is as follows:

Facility: Monsanto Chemical Company.

Location: Dayton, Ohio.

Job Titles and/or Job Duties: Directors and subordinates, physicists, chemists, technicians, and workers.

Period of Employment: 1943–1949.

FOR FURTHER INFORMATION CONTACT: Larry Elliott, Director, Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health, 4676 Columbia Parkway, MS C–46, Cincinnati, OH 45226, Telephone 513–533–6800 (this is not a toll-free number). Information requests can also be submitted by e-mail to *OCAS@CDC.GOV*.

John Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. E6–7777 Filed 5–19–06; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Privacy Act of 1974; Report of a New System of Records

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Notice of a New System of Records (SOR).

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, we are proposing to establish a new SOR titled, ''Organ Procurement Organizations System (OPOS), System No. 09–70–0575.'' The Organ Procurement Organization (OPO) Certification Act of 2000 (§ 701 of Pub. L. 106–505) directs the Secretary of HHS to establish regulations that provide the statutory qualifications and requirements that an OPO must meet in order for organ procurement costs to be reimbursed under the Medicare and Medicaid programs. As part of the efficient administration of this program, CMS is charged with the responsibility to conduct investigations, analysis, and reporting of adverse events that are described as an untoward, undesirable, and unanticipated event that causes death or serious injury. At this time, individually-identifiable data is only requested from OPOs under two circumstances: (1) Due to the suspicion that an infectious disease has been transmitted to a recipient; and (2) when there has been a complaint alleged against an OPO. CMS regional office survey and certification staff would request individually-identifiable data to complete the investigation. Due to certain investigatory activities related to this system, CMS proposes to exempt this system from the notification, access, correction and amendment provisions of the Privacy Act of 1974.

The purpose of this system is to collect and maintain individually identifiable information pertaining to complaint allegations filed by a complainant, beneficiary, or providers of services made against OPOs, information gathered during the complaint investigation, findings and results of the investigation, and correspondence relating to the outcome of the investigation. Information retrieved from this system will also be disclosed to: (1) Support regulatory, reimbursement, and policy functions performed within the agency, or by a contractor, consultant or grantee; (2) assist another Federal or state agency in the enforcement of OPO regulations where sharing the information is necessary to complete the processing of a complaint, contribute to the accuracy of CMS's proper payment of Medicare benefits, and/or enable such agency to administer a Federal health benefits program; (3) support constituent requests made to a Congressional representative; and (4) support litigation involving the agency. We have provided background information about the modified system in the ''Supplementary Information'' section below. Although the Privacy Act requires only that CMS provide an opportunity for interested persons to comment on the proposed routine uses, CMS invites comments on all portions of this notice. See ''Effective Dates'' section for comment period.

DATES: *Effective Date:* CMS filed a new SOR report with the Chair of the House

Committee on Government Reform and Oversight, the Chair of the Senate Committee on Homeland Security & Governmental Affairs, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on May 15, 2006. To ensure that all parties have adequate time in which to comment, the new system will become effective 30 days from the publication of the notice, or 40 days from the date it was submitted to OMB and the Congress, whichever is later. We may defer implementation of this system or one or more of the routine use statements listed below if we receive comments that persuade us to defer implementation.

ADDRESSES: The public should address comment to the CMS Privacy Officer, Mail Stop N2–04–27, 7500 Security Boulevard, Baltimore, Maryland 21244–1850. Comments received will be available for review at this location, by appointment, during regular business hours, Monday through Friday from 9 a.m.–3 p.m., eastern daylight time.

FOR FURTHER INFORMATION CONTACT: Michele Walton, 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. She can be reached by telephone at (410) 786–3353, or via e-mail at *Michele.Walton@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION: OPOs play a crucial role in ensuring that an immensely valuable, but scarce resource—transplantable human organs—become available to seriously ill patients who are on a waiting list for an organ transplant. OPOs are responsible for identifying potential organ donors and for obtaining as many organs as possible from those donors. They are also responsible for ensuring that the organs they obtain are properly preserved and quickly delivered to a suitable recipient awaiting transplantation. Therefore, OPO performance is a critical element of the organ transplant system in the United States. An OPO that is efficient in procuring organs and delivering them to recipients will, quite literally, save more lives than an ineffective OPO.

CMS believes that OPOs will continue to improve their performance. CMS has four Regional OPO Coordinators, who work directly with the OPOs to increase organ donation rates by assisting them in developing and implementing quality assessment and performance improvement programs. In addition, they also make periodic quality visits to identify areas in which an OPO needs to improve. The CMS Regional OPO Coordinators collaborate with the Health Resources and Services Administration, the OPOs, and the hospitals to ensure the continuous implementation of best practices identified through the Organ Donation Breakthrough Collaborative (the Collaborative). However, the Collaborative is a voluntary initiative and, as such, has no enforcement mechanism.

Pursuant to the Health Insurance Portability and Accountability Act (HIPAA), individually-identifiable data is protected from disclosure to third parties, unless an individual has given his or her permission for the information to be disclosed, or the disclosure falls under an exception or permissible use. At this time, individually-identifiable data is only requested from OPOs under two circumstances. This data would be requested whenever there is an investigation due to the suspicion that an infectious disease has been transmitted to a recipient. The request for this data falls under the public health exception in HIPAA. The second is when there has been a complaint alleged against an OPO. CMS is required to investigate complaints made against OPOs. The regional office survey and certification staff would request individually-identifiable data to complete the investigation. The request for this data would be covered under the oversight exception in HIPAA.

I. Description of the Proposed System of Records

A. Statutory and Regulatory Basis for SOR

Authority for this system is given under the Organ Procurement Organization Certification Act of 2000 (§ 701 of Pub. L. 106–505) and § 219 of the Conference Report accompanying the Consolidated Appropriations Act, 2001 (Pub. L. 106–554) containing identical provisions that amended § 371(b) (1) of the Public Health Service (PHS) Act (42 U.S.C. 273(b) (1)). Authority is also given under §§ 1102 and 1138 of the Social Security Act (the Act) (42 U.S.C. 1302, and 42 U.S.C. 1320b–8), § 1138(b) of the Act also specifies that an OPO must operate under a grant made under § 371(a) of the PHS Act.

B. Collection and Maintenance of Data in the System

OPOS will maintain a file of complaint allegations filed by a complainant, beneficiary, or providers of services made against OPOs, information gathered during the complaint investigation, findings and results of the investigation, and correspondence relating to the investigation. The collected information will contain name, address, telephone number, health insurance claim number, geographic location, as well as, background information relating to Medicare or Medicaid issues of the complainant.

II. Agency Policies, Procedures, and Restrictions on the Routine Use

A. Agency Policies, Procedures, and Restrictions on the Routine Use

The Privacy Act permits us to disclose information without an individual's consent if the information is to be used for a purpose that is compatible with the purpose(s) for which the information was collected. Any such disclosure of data is known as a ''routine use.'' The government will only release OPOS information that can be associated with an individual as provided for under ''Section III. Proposed Routine Use Disclosures of Data in the System.'' Both identifiable and non-identifiable data may be disclosed under a routine use.

We will only collect the minimum personal data necessary to achieve the purpose of OPOS. CMS has the following policies and procedures concerning disclosures of information that will be maintained in the system. Disclosure of information from the SOR will be approved only to the extent necessary to accomplish the purpose of the disclosure and only after CMS:

1. Determines that the use or disclosure is consistent with the reason that the data is being collected, e.g., to collect and maintain individually identifiable information pertaining to complaint allegations filed by a complainant, beneficiary, or providers of services made against OPOs, information gathered during the complaint investigation, findings and results of the investigation, and correspondence relating to the outcome of the investigation.

2. Determines that:

a. The purpose for which the disclosure is to be made can only be accomplished if the record is provided in individually identifiable form;

b. The purpose for which the disclosure is to be made is of sufficient importance to warrant the effect and/or risk on the privacy of the individual that additional exposure of the record might bring; and c. There is a strong probability that the proposed use of the data would in fact accomplish the stated purpose(s).

3. Requires the information recipient to:

a. Establish administrative, technical, and physical safeguards to prevent unauthorized use of disclosure of the record;

b. Remove or destroy at the earliest time all patient-identifiable information; and

c. Agree to not use or disclose the information for any purpose other than the stated purpose under which the information was disclosed.

4. Determines that the data are valid and reliable.

III. Proposed Routine Use Disclosures of Data in the System

A. The Privacy Act allows us to disclose information without an individual's consent if the information is to be used for a purpose that is compatible with the purpose(s) for which the information was collected. Any such compatible use of data is known as a ''routine use.'' The proposed routine uses in this system meet the compatibility requirement of the Privacy Act. We are proposing to establish the following routine use disclosures of information maintained in the system:

1. To agency contractors, consultants or grantees who have been engaged by the agency to assist in the performance of a service related to this system of records and who need to have access to the records in order to perform the activity.

We contemplate disclosing information under this routine use only in situations in which CMS may enter into a contractual or similar agreement with a third party to assist in accomplishing CMS function relating to purposes for this system.

CMS occasionally contracts out certain of its functions when doing so would contribute to effective and efficient operations. CMS must be able to give contractors, consultants or grantees whatever information is necessary for the contractors, consultants or grantees to fulfill its duties. In these situations, safeguards are provided in the contract prohibiting the contractors, consultants or grantees from using or disclosing the information for any purpose other than that described in the contract and requires the contractors, consultants or grantees to return or destroy all information at the completion of the contract.

2. To another Federal or state agency to:

a. Assist in the enforcement of Organ Procurement Organizations regulations for violations of Conditions for Coverage for Organ Procurement Organizations where sharing the information is necessary to complete the processing of a complaint,

b. Contribute to the accuracy of CMS's proper payment of Medicare benefits, and/or

c. Enable such agency to administer a Federal health benefits program, or as necessary to enable such agency to fulfill a requirement of a Federal statute or regulation that implements a health benefits program funded in whole or in part with Federal funds.

Other Federal or state agencies in their administration of a Federal health program may require OPOS information in order to investigate complaint allegations, evaluate information gathered during the complaint investigation, review findings and results of the investigation relating to the enforcement of OPO regional office investigations.

3. To a member of Congress or to a Congressional staff member in response to an inquiry of the Congressional office made at the written request of the constituent about whom the record is maintained.

Beneficiaries sometimes request the help of a member of Congress in resolving an issue relating to a matter before CMS. The member of Congress then writes CMS, and CMS must be able to give sufficient information to be responsive to the inquiry.

4. To the Department of Justice (DOJ), court or adjudicatory body when:

a. The agency or any component thereof, or

b. Any employee of the agency in his or her official capacity, or

c. Any employee of the agency in his or her individual capacity where the DOJ has agreed to represent the employee, or

d. The United States Government is a party to litigation or has an interest in such litigation, and by careful review, CMS determines that the records are both relevant and necessary to the litigation and that the use of such records by the DOJ, court or adjudicatory body is compatible with the purpose for which the agency collected the records.

Whenever CMS is involved in litigation, and occasionally when another party is involved in litigation and CMS' policies or operations could be affected by the outcome of the litigation, CMS would be able to disclose information to the DOJ, court or adjudicatory body involved.

B. Additional Provisions Affecting Routine Use Disclosures. To the extent this system contains Protected Health Information (PHI) as defined by HHS regulation ''Standards for Privacy of Individually Identifiable Health Information'' (45 CFR parts 160 and 164, subparts A and E) 65 FR 82462 (12–28–00). Disclosures of such PHI that are otherwise authorized by these routine uses may only be made if, and as, permitted or required by the ''Standards for Privacy of Individually Identifiable Health Information.'' (See 45 CFR 164.512(a)(1)).

In addition, our policy will be to prohibit release even of data not directly identifiable, except pursuant to one of the routine uses or if required by law, if we determine there is a possibility that an individual can be identified 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).

IV. 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.

V. Effects of the Proposed System of Records on Individual Rights

CMS proposes to establish this system in accordance with the principles and requirements of the Privacy Act and will collect, use, and disseminate information only as prescribed therein. Data in this system will be subject to the authorized releases in accordance with the routine uses identified in this system of records.

CMS will take precautionary measures to minimize the risks of unauthorized access to the records and the potential harm to individual privacy or other personal or property rights of patients whose data are maintained in the system. CMS will collect only that information necessary to perform the system's purpose. In addition, CMS will make disclosures from the system only with consent of the subject individual, or his/her legal representative, or in accordance with an applicable exception provision of the Privacy Act. CMS, therefore, does not anticipate an unfavorable effect on individual privacy as a result of information relating to individuals.

Dated: May 15, 2006.

Charlene Frizzera,

Acting Chief Operating Officer, Centers for Medicare & Medicaid Services.

SYSTEM NO. 09–70–0575

SYSTEM NAME:

''Organ Procurement Organizations System (OPOS)'' HHS/CMS/OCSQ.

SECURITY CLASSIFICATION:

Level Three Privacy Act Sensitive Data.

SYSTEM LOCATION:

Centers for Medicare & Medicaid Services (CMS) Central Office and Regional Offices, and at various contractor locations.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

OPOS will maintain a file of complaint allegations filed by a complainant, beneficiary, or providers of services made against OPOs, information gathered during the complaint investigation, findings and results of the investigation, and correspondence relating to the investigation.

CATEGORIES OF RECORDS IN THE SYSTEM:

The collected information will contain name, address, telephone number, health insurance claim number (HICN), geographic location, as well as, background information relating to Medicare or Medicaid issues of the complainant.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Authority for this system is given under the Organ Procurement Organization Certification Act of 2000 (§ 701 of Pub. L. 106–505) and § 219 of the Conference Report accompanying the Consolidated Appropriations Act, 2001 (Pub. L. 106–554) containing identical provisions that amended § 371(b)(1) of the Public Health Service (PHS) Act (42 U.S.C. 273(b)(1)). Authority is also given under §§ 1102 and 1138 of the Social Security Act (the Act) (42 U.S.C. 1302, and 42 U.S.C. 1320b–8), § 1138(b) of the Act also specifies that an OPO must operate under a grant made under § 371(a) of the PHS Act.

PURPOSE(S) OF THE SYSTEM:

The purpose of this system is to collect and maintain individually identifiable information pertaining to complaint allegations filed by a complainant, beneficiary, or providers of services made against OPOs, information gathered during the complaint investigation, findings and results of the investigation, and correspondence relating to the outcome of the investigation. Information retrieved from this system will also be disclosed to: (1) Support regulatory, reimbursement, and policy functions performed within the agency, or by a contractor, consultant or grantee; (2) assist another Federal or state agency in the enforcement of OPO regulations where sharing the information is necessary to complete the processing of a complaint, contribute to the accuracy of CMS's proper payment of Medicare benefits, and/or enable such agency to administer a Federal health benefits program; (3) support constituent requests made to a Congressional representative; and (4) support litigation involving the agency.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OR USERS AND THE PURPOSES OF SUCH USES:

C. The Privacy Act allows us to disclose information without an individual's consent if the information is to be used for a purpose that is compatible with the purpose(s) for which the information was collected. Any such compatible use of data is known as a ''routine use.'' The proposed routine uses in this system meet the compatibility requirement of the Privacy Act. We are proposing to establish the following routine use disclosures of information maintained in the system:

1. To agency contractors, consultants or grantees who have been engaged by the agency to assist in the performance of a service related to this system of records and who need to have access to the records in order to perform the activity.

2. To another Federal or state agency to:

a. Assist in the enforcement of Organ Procurement Organizations regulations for violations of Conditions for Coverage for Organ Procurement Organizations where sharing the information is necessary to complete the processing of a complaint,

b. Contribute to the accuracy of CMS's proper payment of Medicare benefits, and/or

c. Enable such agency to administer a Federal health benefits program, or as necessary to enable such agency to fulfill a requirement of a Federal statute or regulation that implements a health benefits program funded in whole or in part with Federal funds.

3. To a member of Congress or to a Congressional staff member in response to an inquiry of the Congressional office made at the written request of the constituent about whom the record is maintained.

4. To the Department of Justice (DOJ), court or adjudicatory body when:

a. The agency or any component thereof, or

b. Any employee of the agency in his or her official capacity, or

c. Any employee of the agency in his or her individual capacity where the DOJ has agreed to represent the employee, or

d. The United States Government is a party to litigation or has an interest in such litigation, and by careful review, CMS determines that the records are both relevant and necessary to the litigation and that the use of such records by the DOJ, court or adjudicatory body is compatible with the purpose for which the agency collected the records.

D. Additional Provisions Affecting Routine Use Disclosures. To the extent this system contains Protected Health Information (PHI) as defined by HHS regulation ''Standards for Privacy of Individually Identifiable Health Information'' (45 CFR parts 160 and 164, subparts A and E) 65 FR 82462 (12–28–00). Disclosures of such PHI that are otherwise authorized by these routine uses may only be made if, and as, permitted or required by the ''Standards for Privacy of Individually Identifiable Health Information.'' (See 45 CFR 164.512(a)(1)).

In addition, our policy will be to prohibit release even of data not directly identifiable, except pursuant to one of the routine uses or if required by law, if we determine there is a possibility that an individual can be identified

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),