studies to assess the carcinogenic potency of a class of agents with dioxin-like activity

- TR 558 3,3′,4,4′-Tetrachloroazobenzene (CASRN 14047–09–7)
  - Impurity in dichloroaniline and in herbicides derived from dichloroaniline; evaluated as part of the Dioxin Toxic Equivalency Factor Evaluation for compounds with dioxin-like activity
- TR 560 Androstenedione (CASRN 63–05–8)
  - Dietary supplement that was used by athletes during training, but now is banned for over-the-counter sale
- TR 557 β-Myrcene (CASRN 123–35–3)
  - Intermediate in the commercial production of terpene alcohols, which are intermediates in the production of aroma and flavoring chemicals; used as a scent in cosmetics and soaps and as a flavoring additive in food and beverages; major constituent of hop and bay oils
- TR 555 Tetralin (CASRN 119–64–2)
  - Used as an industrial solvent for paints, waxes, polishes, pesticides, rubber, asphalt, and aromatic hydrocarbons; used as an insecticide; derived from naphthalene
- TR 562 Goldenseal Root Powder (CASRN goldensealRT)
  - Natural herbal remedy for which there is little or no toxicity data

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BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Assistant Secretary for Planning and Evaluation; Privacy Act of 1974; Report of New System of Records

AGENCY: Office of the Assistant Secretary for Planning and Evaluation (ASPE).

ACTION: Notice of new System of Records (SOR).

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, the Office of Assistant Secretary for Planning and Evaluation (ASPE) is proposing to establish a new system of records, called the Partnership for Long Term Care Data Set. The Partnership allows states to offer special Medicaid asset disregards to persons purchasing specially certified long term care insurance policies. This program and the data collection were established by the Deficit Reduction Act of 2005—Section 6021. Although the Privacy Act requires only that the ''routine uses'' portion of the system be published for comment, ASPE invites comments on all portions of this notice. Elsewhere in today's **Federal Register**, a related final rulemaking establishing the State Long Term Care Partnership: Reporting Requirements for Insurers.

DATES: *Effective Date:* The new system of records, including routine uses, will become effective January 27, 2009 unless ASPE receives comments that require alteration to this notice.

ADDRESSES: Address comments to the Privacy Act Officer, Office of Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, 200 Independence Ave, SW., Room Number 436E.2, Washington, DC 20201. 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 Time Zone. Call 202–205–8999 for appointment.

FOR FURTHER INFORMATION CONTACT: Hunter McKay, Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, 200 Independence Ave, SW., Room Number 424E, Washington, DC 20201. The telephone number is (202) 205–8999 and the e-mail address is *hunter.mckay@hhs.gov.*

SUPPLEMENTARY INFORMATION:

The Partnership for Long Term Care initiative was mandated by Section 6021 of Public Law 109–171, the Deficit Reduction Act of 2005 (DRA). The Partnership allows states to offer special Medicaid asset disregards to persons purchasing specially certified long term care insurance policies. The asset disregards allow program participants to keep additional assets should they need to apply for Medicaid coverage of long term care. DRA also mandates the use of a standard reporting system for all insurers participating in a state Partnership for Long Term Care program through a Medicaid State Plan Amendment approved after May 14, 1993. Participating insurers are required to report data on Partnership policy purchasers, features of the policies they purchase, and, selected claims information.

The Privacy Act permits us to disclose information without the consent of individuals under a ''routine use.'' A routine use is a disclosure outside of the Department of Health and Human Services that is compatible with the purpose for which we collected the information. The proposed routine uses in the new system of records meet the compatibility criterion of the statute.

Dated: November 21, 2008.

Mary M. McGeein,

Principal Deputy Assistant Secretary for Planning and Evaluation.

SYSTEM NO.
09–90–0085

SYSTEM NAME:

Partnership for Long Term Care Data Set.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Thomson Reuters, 610 Opperman Drive, Eagan, Minnesota 55123.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Purchasers of long term care insurance policies certified by a selected state (Medicaid state plan amendment approved after May 14, 1993) insurance commissioner as meeting the state's Partnership's requirements for certification.

CATEGORIES OF RECORDS IN THE SYSTEM:

- ◊ Name
- ◊ Address
- ◊ Social Security Number
- ◊ Date of Birth
- ◊ Long Term Care Insurance Policy Information
  - Long Term Care Insurance Company
  - Long Term Care Insurance Policy Number
  - Type of Policy (Group, Individual and Comprehensive, Nursing Home Only)
  - Policy Issue State
  - Lifetime Maximum Benefit
  - Duration of Insurance Benefits (dollars or days)
  - Daily Benefit Amount
  - Inflation Protection Feature (required by DRA for select ages)
- ◊ Claims Information
  - Qualifying Condition for Claim (ADL, Cognitive Impairment, Other)
  - Benefits Payment by Type of Service (institutional or home)
  - Remaining Lifetime Maximum Benefits (by service type when multiple pools)

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The authority for this system of records is contained in Section 6021 of the Deficit Reduction Act of 2005, Public Law 109–171, 42 U.S.C. 1396p note.

PURPOSE(S) OF THE SYSTEM:

The purpose of the system of records is to support Medicaid eligibility determinations for persons participating in a Partnership for long term care program.

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

Section 552a(b)(3) of the Privacy Act permits an agency to establish disclosures not anticipated by the statute itself, compatible with the purpose for which the information was collected, under which the information may be released without the consent of the individual to whom the information pertains. ASPE is identifying the following routine disclosures for information held in the Partnership for Long Term Care Data Set. Each proposed disclosure of information under these routine uses will be evaluated to ensure that the disclosure is legally permissible, including, but not limited to, ensuring that the purpose of the disclosure is compatible with the purpose for which the information was collected. Disclosure may be made under the following circumstances.

1. Disclosure may be made to a State, local, tribal or other public authority for the purpose of verifying Partnership program participation and calculation of the amount of the Medicaid Partnership asset disregard.

2. Disclosure may be made to the Department of Justice when: (a) The agency or any component thereof; or (b) any employee of the agency in his or her official capacity; (c) any employee of the agency in his or her individual capacity where agency or the Department of Justice 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, the agency determines that the records are both relevant and necessary to the litigation and the use of such records by the Department of Justice is therefore deemed by the agency to be for a purpose that is compatible with the purpose for which the agency collected the records.

3. Disclosure may be made to a court or adjudicative body in a proceeding when: (a) The agency or any component thereof; or (b) any employee of the agency in his or her official capacity; (c) any employee of the agency in his or her individual capacity where agency or the Department of Justice 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, the agency determines that the records are both relevant and necessary to the litigation and the use of such records is therefore deemed by the agency to be for a purpose that is compatible with the purpose for which the agency collected the records.

4. When a record on its face, or in conjunction with other records, indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule, or order issued pursuant thereto, disclosure may be made to the appropriate public authority, whether Federal, foreign, state, local, tribal, or otherwise responsible for enforcing, investigating, or prosecuting such violation or charged with enforcing, or implementing the statute, rule, regulation, or order issued pursuant hereto, if the information disclosed is relevant to any enforcement, regulatory, investigative or prosecutorial responsibility of the receiving entity.

5. Disclosure may be made 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. The Member of Congress does not have any greater authority to obtain records than the individual would have if requesting the record directly.

6. Disclosure may be made to agency contractors, grantees, or volunteers who have been engaged to assist the agency in the performance of a contract service, grant, cooperative agreement or other activity related to this system of records and who need to have access to the records in order to perform the activity. Recipients shall be required to comply with the requirements of the Privacy Act of 1974, as amended 5 U.S.C. 552a.

7. Disclosure may be made to an individual or organization conducting a research, demonstration, or evaluation project related to long term care financing generally, the performance of long term care insurance or Partnership programs, or for the purposes of determining, evaluating, assessing cost effectiveness, or quality of the long term care services provided through a Partnership program.

8. To another Federal or state agency for the purpose of operating the Medicaid program or otherwise assisting states in the administration of those portions of the Medicaid program with direct connection to state Partnership programs.

9. To appropriate federal agencies and Department contractors that have a need to know the information for the purpose of assisting the Department's efforts to respond to a suspected or confirmed breach of the security or confidentiality of information maintained in this system of records, and the information disclosed is relevant and necessary for that assistance.

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

STORAGE:

All records are stored on paper or magnetic media.

RETRIEVABILITY:

The records are retrieved by the long term care insurance policy number, name, social security number, or a combination of these.

SAFEGUARDS:

For computerized records, safeguards established in accordance with Department standards and National Institute of Standards and Technology guidelines (e.g., security codes) will be used, limiting access to authorized personnel. System security policy and practices are established in accordance with HHS, Information Resources Management (IRM) Circular #10, Automated Information Systems Security Program; HCFA Automated Information System (AIS) Guide, Systems Security Policies; and OMB Circular No. A–130 (revised), Appendix III.

RETENTION AND DISPOSAL:

We are working with the National Archives and Records Administration (NARA) to determine the appropriate retention schedule. Due to the nature of these records, we expect them to be preserved for at least 20 years after the death of the policyholder. When the retention period has been approved by NARA, we will amend this notice.

SYSTEM MANAGER(S) AND ADDRESS:

Hunter McKay, Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, 200 Independence Ave, SW., Room Number 424E, Washington, DC 20201.

NOTIFICATION PROCEDURE:

For purpose of notification, individuals may write the system manager, who will require the insured's name, insurance company name, insurance policy number, and, for verification purposes, date of birth, to ascertain whether or not the individual's record is in the system. (These notification procedures are in accordance with Department regulation 45 CFR part 5b.)

RECORD ACCESS PROCEDURE:

Same as notification procedures. Requestors should also reasonably specify the record contents being

sought. (These access procedures are in accordance with the Department regulation 45 CFR 5b.5(a)(2).)

CONTESTING RECORD PROCEDURES:

Contact the system manager named above, and reasonably identify the record 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.)

RECORD SOURCE CATEGORIES:

Information is reported by private long term care insurance companies selling policies that have been certified by a state insurance commissioner as Partnership qualified in a state that had obtained a Medicaid state plan amendment approved after of May 14, 1993.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. E8–28345 Filed 12–17–08; 8:45 am]

BILLING CODE 4154–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0613]

Clinical Studies of Safety and Effectiveness of Orphan Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA) Office of Orphan Product Development (OPD) is providing notice of a funding opportunity announcement for Federal assistance. The goal of the OPD grant program is to support the clinical development of products for use in rare diseases or conditions where no current therapy exists or where the proposed product will be superior to the existing therapy. FDA provides grants for clinical studies on safety and/or effectiveness that will either result in, or substantially contribute to, market approval of these products.

DATES: See section IV.E of the **SUPPLEMENTARY INFORMATION** section for application submission dates.

FOR FURTHER INFORMATION CONTACT:

Scientific/Research Contact: Katherine Needleman, Office of Orphan Products Development, Food and Drug Administration (HF–35), rm. 6A–55, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3666, e-mail: *katherine.needleman@fda.hhs.gov*.

Financial/Grants Management Contact: Vieda Hubbard, Office of Acquisitions & Grant Services, 5630 Fishers Lane (HFA–500), rm. 2104, Rockville, MD 20857, 301–827–7177, e-mail: *vieda.hubbard@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

Research Project Grants (R01)
Request for Application (RFA) Number: RFA–FD–09–001
Catalog of Federal Domestic Assistance Number(s): 93.103

A. Research Objectives

1. Background

OPD was created to identify and promote the development of orphan products. Orphan products are drugs, biologics, medical devices, and foods for medical purposes that are indicated for a rare disease or condition (that is, one with prevalence, not incidence, of fewer than 200,000 people in the United States). Diagnostics and vaccines will qualify for orphan status only if the U.S. population to whom they will be administered is fewer than 200,000 people per year.

2. Research Objectives

The goal of FDA's OPD grant program is to support the clinical development of products for use in rare diseases or conditions where no current therapy exists or where the proposed product will be superior to the existing therapy. FDA provides grants for clinical studies on safety and/or effectiveness that will either result in, or substantially contribute to, market approval of these products. Applicants must include, in the application's ''Background and Significance'' section, documentation to support the estimated prevalence of the orphan disease or condition (or in the case of a vaccine or diagnostic, information to support the estimates of how many people will be administered the diagnostic or vaccine annually) and an explanation of how the proposed study will either help gain product approval or provide essential data needed for product development.

See section VII.A of this document for policies related to this announcement.

II. Award Information

A. Mechanism of Support

Support will be in the form of a research project (R01) grant. The R01 grant is an award made to support a discrete, specified, circumscribed project to be performed by the named investigator(s) in an area representing the investigator's specific interest and competencies, based on the mission of FDA. The Project Director/Principal Investigator (PD/PI) will be solely responsible for planning, directing, and executing the proposed project.

All awards will be subject to all policies and requirements that govern the research grant programs of the Public Health Service (PHS) as incorporated in the Department of Health and Human Services (HHS) Grants Policy Statement, dated January 1, 2007 (*http://www.hhs.gov/grantsnet/adminis/gpd/index.htm*), including the provisions of 42 CFR part 52 and 45 CFR parts 74 and 92. The regulations issued under Executive Order 12372 do not apply to this program. The National Institutes of Health (NIH) modular grant program does not apply to this FDA grant program. All grant awards are subject to applicable requirements for clinical investigations imposed by sections 505, 512, and 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 360b, and 360e), section 351 of the PHS Act, regulations issued under any of these sections, and other applicable HHS statutes and regulations regarding human subject protection.

Except for applications for studies of medical foods that do not need premarket approval, FDA will only award grants to support premarket clinical studies to determine safety and effectiveness for approval under section 505 or 515 of the Federal Food, Drug, and Cosmetic Act or safety, purity, and potency for licensing under section 351 of the PHS Act. FDA will support the clinical studies covered by this notice under the authority of section 301 of the PHS Act (42 U.S.C. 241). FDA's research program is described in the Catalog of Federal Domestic Assistance (CFDA) No. 93.103.

B. Funds Available

1. Award Amount

Of the estimated FY 2010 funding ($14.1 million), approximately $10 million will fund noncompeting continuation awards, and approximately $4.1 million will fund 10 to 12 new awards, subject to availability of funds. It is anticipated that funding for the number of noncompeting continuation awards and new awards in FY 2011 will be similar to FY 2010. Grants will be awarded up to $200,000 or up to $400,000 in total (direct plus indirect) costs per year for up to 4 years. Please note that the dollar limitation will apply to total costs, not direct costs, as in