Federal Register (FR) 6435 (February 20, 1996), and OMB guidelines pertaining to computer matching at 54 FR 25818 (June 19, 1989).

Prior to 1991, CHAMPUS entitlement terminated when any individual became eligible for Medicare Part A on a non-premium basis. The National Defense Authorization Act(s) (NDAA) for Fiscal Years (FY) 1992 and 1993 (Pub. L. 102–190) § 704, provide for reinstatement of CHAMPUS as second payer for beneficiaries entitled to Medicare on the basis of disability/End Stage Renal Disease (ESRD) only if they also enroll in Part B.

This agreement implements the information matching provisions of the NDAA, FY 2001 (Pub. L. 106–398) Sections 711 and 712; the NDAA, FY 1993 (Pub. L. 102–484) Section 705; and the NDAA, FY 1992 (Pub. L. 102–190) Sections 704 and 713.

Section 732 of the FY 1996 NDAA (Pub. L. 104–106), directed the administering Secretaries to develop a mechanism for notifying beneficiaries of their ineligibility for CHAMPUS when loss of eligibility is due to disability status.

PURPOSE (S) OF THE MATCHING PROGRAM:

The purpose of this agreement is to establish the conditions, safeguards and procedures under which CMS will disclose Medicare enrollment information to the DoD, DMDC, DEERS, and Health Affairs/TMA. The disclosure by CMS will provide TMA with the information necessary to determine if Military Health System (MHS) beneficiaries (other than dependents of active duty personnel), who are Medicare eligible, are eligible to receive continued military health care benefits. This disclosure will provide TMA with the information necessary to meet the Congressional mandate outlined in legislative provisions in the NDAA listed above.

Current law requires TMA to discontinue military health care benefits to MHS beneficiaries who are Medicare eligible and under the age of 65 when they become eligible for Medicare Part A because of disability/ESRD unless they are enrolled in Medicare Part B. Current law also requires TMA to provide health care and medical benefits to MHS beneficiaries who are Medicare eligible (commonly referred to as the dual eligible population) over the age of 65 who are enrolled in the supplementary medical insurance program under Part B of the Medicare program. This CMA will combine both groups of the MHS beneficiary population described above into one single database to more effectively carry out this matching program. In order for TMA to meet the requirements of current law, CMS agrees to disclose certain Part A and Part B enrollment data on this dual eligible population, which will be used to determine a beneficiary's eligibility for care under CHAMPUS/TRICARE. DEERS will receive the results of the computer match and provide the information to TMA for use in its matching program.

This computer matching agreement supersedes all existing data exchange agreements between CMS and DMDC applicable to the exchange of personal data for purposes of disclosing enrollment and eligibility information for MHS beneficiaries who are Medicare eligible.

CATEGORIES OF RECORDS AND INDIVIDUALS COVERED BY THE MATCH:

DEERS will furnish CMS with an electronic file on a monthly basis extracted from the DEERS' systems of records containing social security numbers (SSN) for all MHS beneficiaries who may also be eligible for Medicare benefits. CMS will match the DEERS finder file against its "Medicare Beneficiary Database" system of records (System No. 09–70–0536), and will validate the identification of the beneficiary and provide the Health Insurance Claim Number that matches against the SSN and date of birth provided by DEERS, and also provide the Medicare Part A entitlement status and Part B enrollment status of the beneficiary. CMS's data will help TMA to determine a beneficiary's eligibility for continued care under TRICARE. DEERS will receive the results of the computer match and provide the information provided to TMA for use in its program.

DESCRIPTION OF RECORDS TO BE USED IN THE MATCHING PROGRAM:

DoD will use the SOR identified as DMDC 02 DoD, entitled "Defense Enrollment Eligibility Reporting System," at 74 **Federal Register** (FR) 39657 (August 7, 2009). SSNs of DoD beneficiaries will be released to CMS pursuant to the routine use set forth in the system notice, which provides that data may be released to HHS "for support of the DEERS enrollment process and to identify individuals not entitled to health care."

Identification and Medicare status of DoD eligible beneficiaries will be provided to TMA to implement the statutory program. Therefore, eligibility information may also be maintained in the SOR identified as DHA 07, entitled "Military Health Information System (MHIS)," at 71 FR 16127 (March 30, 2006).

The release of the data for CMS is covered under the "Enrollment Database," System No. 09–70–0502 published in the **Federal Register** at 73 FR 10249 (February 26, 2008). Matched data will be released to DEERS pursuant to the routine use number 2 as set forth in the system notice.

INCLUSIVE DATES OF THE MATCH:

The Matching Program shall become effective no sooner than 40 days after the report of the Matching Program is sent to OMB and Congress, or 30 days after publication in the **Federal Register**, which ever is later. The matching program will continue for 18 months from the effective date and may be renewed for an additional 12 month period as long as the statutory language for the match exists and other conditions are met.

[FR Doc. 2011–6273 Filed 3–16–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Affordable Care Act Tribal Maternal, Infant, and Early Childhood Home Visiting Program Needs Assessment and Plan for Responding to Identified Needs.

OMB No.: New Collection.

Description: Section 511(h)(2)(A) of Title V of the Social Security Act, as added by Section 2951 of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148, Affordable Care Act or ACA), authorizes the Secretary of HHS to award grants to Indian Tribes (or a consortium of Indian Tribes), Tribal Organizations, or Urban Indian Organizations to conduct an early childhood home visiting program. The legislation sets aside 3 percent of the total ACA Maternal, Infant, and Early Childhood Home Visiting Program appropriation (authorized in Section 511(j)) for grants to Tribal entities and requires that the Tribal grants, to the greatest extent practicable, be consistent with the requirements of the Maternal, Infant, and Early Childhood Home Visiting Program grants to States and territories (authorized in Section 511(c)), and include conducting a needs assessment and establishing benchmarks.

The Administration for Children and Families, Office of Child Care, in

collaboration with the Health Resources and Services Administration, Maternal and Child Health Bureau, recently awarded grants for the Tribal Maternal, Infant, and Early Childhood Home Visiting Program (Tribal Home Visiting). The Tribal Home Visiting grant awards will support 5-year cooperative agreements to conduct community needs assessments, plan for and implement high-quality, culturally-relevant, evidence-based home visiting programs in at-risk Tribal communities, and participate in research and evaluation activities to build the knowledge base on home visiting among Native populations.

In Phase 1 (Year 1) of the cooperative agreement, grantees must (1) conduct a comprehensive community needs assessment and (2) develop a plan and begin to build capacity to respond to identified needs. Grantees will be expected to submit the needs assessment and plan for responding to identified needs through an evidence-based home visiting program within 10 months of the Year 1 award date. Grantees may engage in needs assessment, planning, and capacity-building activities during Phase 1, but will not fully implement their plan and/or begin serving children and families through high-quality, evidence-based home visiting programs. Pending successful Phase 1 activities and submission (within 10 months of Year 1 award date) of a non-competing continuation application that includes a needs assessment and approvable plan for responding to identified needs, funds will be provided for Phase 2 (Implementation Phase, Years 2–5)

Respondents: Affordable Care Act Tribal Maternal, Infant, andEarly Childhood Home Visiting Year 1 Grantees.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Needs Assessment and Plan	18	1	100	1,800

Estimated Total Annual Burden Hours: 1,800.

Additional Information:

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, *Attn:* ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. *E-mail address: infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, *Fax:* 202–395–7285, *E-mail: OIRA_SUBMISSION@OMB.EOP.GOV, Attn:* Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2011–6068 Filed 3–16–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–E–0405]

Determination of Regulatory Review Period for Purposes of Patent Extension; ISTODAX

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ISTODAX and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov*. Submit written petitions along with three copies and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product ISTODAX (romidepsin). ISTODAX is indicated for treatment of cutaneous T-cell lymphoma in patients who have received at least one prior systemic therapy. Subsequent