

Romania, Russia, Turkey, and Ukraine on December 29, 2005; Nigeria on February 8, 2006; India on February 22, 2006; Egypt on February 27, 2006; Niger on March 2, 2006; Albania, Azerbaijan, Cameroon, and Burma (Myanmar) on March 15, 2006; and Israel on March 20, 2006.

On March 15, 2006, OIE reported confirmation of highly pathogenic avian influenza H5N1 in poultry in Afghanistan. At this time, HHS/CDC is adding Afghanistan to its current embargo. This action is effective on March 21, 2006, and will remain in effect until further notice.

**SUPPLEMENTARY INFORMATION:**

**Background**

On March 15, 2006, OIE reported confirmation of highly pathogenic avian influenza H5N1 in chickens and turkeys in five provinces of Afghanistan, including Jalalabad, Kabul, Laghman, Vardak and Kunar.

Introduction of birds infected with highly pathogenic avian influenza H5N1 into the United States could lead to outbreaks of disease among birds and among the human population, a significant public health threat. Banning the importation of all avian species from affected countries is an effective means of limiting this threat. HHS/CDC is therefore taking this action to reduce the likelihood of introduction or spread of influenza A H5N1 into the United States.

**Immediate Action**

Therefore, pursuant to 42 CFR 71.32(b), HHS/CDC is amending the February 4, 2004, order to add Afghanistan to the list of countries subject to the order's embargo of birds and products derived from birds. All other portions of the February 4, 2004, order, as further amended on March 10, 2004, September 28, 2004, December 29, 2005, February 8, 2006, February 22, 2006, February 27, 2006, March 2, 2006, March 15, 2006, and March 20, 2006, shall remain in effect until further notice.

Dated: March 23, 2006.

**Julie Louise Gerberding,**

*Director, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Proposed Information Collection Activity; Comment Request**

**Proposed Projects**

*Title:* Evaluation to Determine the Effectiveness of the Public Assistance Reporting Information System (PARIS). *OMB No.* New Collection.

*Description:* The PARIS program is a voluntary information exchange system that allows States and other entities (counties or jurisdictions like the District of Columbia) to submit Medical Assistance, Medicaid, Food Stamp, and Temporary Assistance for Needy Families (TANF) participant data to the Administration for Children and Families (ACF) to be matched with Federal and participating States' databases to detect potential dual participation and improper payments. Launched by ACF in 1997, the PARIS project was developed to provide States with usable data by which they could identify and correct erroneous payments and to promote State partnerships and matching of cross-state data to improve program integrity. There are currently 36 entities participating in the PARIS project (Member States). ACF is encouraging the expansion of PARIS via a grantee program by providing funds to Member States to partner with nonparticipating States to develop the internal organization and mechanisms needed for PARIS participation. An implementation and outcome evaluation of the PARIS program will determine the effectiveness of the program and the

resulting impact on reducing improper payments. Data collected will determine factors affecting program participation, relevant PARIS administrative and implementation information, challenges in implementation, cost of program participation and estimated savings through identified and resolved participant matches.

Health Systems Research, an ACF Contractor conducting the research, will send State-level PARIS Administrators surveys regarding the organization and administration of PARIS, processes used for submitting data, and follow-up protocols. Information obtained through key-informant interviews of Medicaid, TANF, and Food Stamp program officials will provide information regarding relationships among the various stakeholders, opinions on effectiveness of PARIS, and the rationale behind decisions. E-mails sent to States will contain cost-accounting forms, providing cost information on program start-up, submission of data, follow-up of potential participant matches, and will then be verified through telephone interviews with program and fiscal administrators. As part of the final PARIS evaluation, a prospective and retrospective analysis is planned. Collections of prospective information from a sample of States that are not yet committed to permanent participation in PARIS and prospective and retrospective information from States already participating in the program are planned.

Two current PARIS sites and one non-PARIS grantee site will comprise a pilot of the data collection instruments to ensure evaluation questions are clear and elicit salient responses. Findings from the pilot study will inform the final PARIS evaluation tool development.

*Respondents:* Approximately sixteen States will comprise the sample, with an estimated twelve respondents from each State, county or jurisdiction.

**ANNUAL BURDEN ESTIMATES**

Instrument	Number of respondents	Numer of responses per respondent	Average burden hours per response	Total burden hours
State-Level PARIS Administrator Survey .....	16	1	1	16
Medicaid, Food Stamp and TANF Program Officials Key-Informant Interviews .....	160	1	1	160
State Cost-Accounting Forms .....	16	1	1.5	24
Fiscal Administrator Telephone Interviews .....	32	1	1.5	48

*Estimated Total Annual Burden Hours: 248.*

In compliance with the requirements of Section 3506(c)(2)(A) of the

Paperwork Reduction Act of 1995, the Administration for Children and

Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded 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. E-mail address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: March 22, 2006.

**Robert Sargis,**

*Reports Clearance Officer.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2006N-0104]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed

extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting requirements contained in the requirements for submission of labeling for human prescription drugs and biologics in electronic format.

**DATES:** Submit written or electronic comments on the collection of information by May 30, 2006.

**ADDRESSES:** Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Karen Nelson, Office Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on

respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

#### Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format (OMB Control Number 0910-0530)—Extension

FDA is requesting that OMB extend approval under the PRA for the information collection contained in the final rule entitled "Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format" (68 FR 69009, December 11, 2003) (the final rule). The final rule amended FDA regulations governing the format in which certain labeling is required to be submitted for FDA review with new drug applications (NDAs), certain biological license applications (BLAs), abbreviated new drug applications (ANDAs), supplements, and annual reports. The final rule required that the content of labeling for prescription drug and biological products required under 21 CFR 201.100(d)(3) be submitted to FDA electronically in a form that FDA can process, review, and archive. Copies of product labeling have been required to be submitted to FDA for review in NDAs, certain BLAs, ANDAs, certain supplements, and annual reports under §§ 314.50, 314.70, 314.81, 314.94, 314.97, 314.98, 601.2, and 601.12 (21 CFR 314.50, 314.70, 314.81, 314.94, 314.97, 314.98, 601.2, and 601.12). Under these regulations, copies of labeling may be submitted electronically or on paper. The final rule added the requirement to submit the content of labeling in electronic format to simplify the drug labeling review process and speed up the approval of labeling changes.

The reporting burden for submitting labeling under §§ 314.50, 314.70, 314.81, 314.94, 314.97, and 314.98 has been estimated by FDA and the collection of information has been approved by OMB under OMB control number 0910-0001, most recently until May 31, 2008. The reporting burden associated with current §§ 601.2 and 601.12 has also been estimated and that collection of information has been approved by OMB under OMB control number 0910-0338, most recently until September 30, 2008. We are not re-estimating these approved burdens in this action. Only the additional reoccurring reporting burdens associated with the electronic submission of the content of labeling in the final rule are estimated in this action.