suppliers maintain in their records and make available to CMS and its agents upon request. Finally, this rule discusses CMS' policy on documentation that may be requested by CMS and its agents to support a Medicare claim for payment. *Form Number:* CMS–10116 (OCN: 0938–0971); *Frequency:* Yearly; *Affected Public:* Private Sector—Business or other for-profits. *Number of Respondents:* 90,521. *Number of Responses:* 173,810. *Total Annual Hours:* 34,762. (For policy questions regarding this collection contact Susan Miller at 410–786–2118. For all other issues call 410–786–1326.)

3. *Type of Information Collection Request:* New collection; *Title of Information Collection:* End Stage Renal Disease (ESRD) System Access Request Form; *Use:* Within CMS, the Office of Clinical Standards and Quality is developing a new suite of systems to support the End Stage Renal Disease (ESRD) program. Due to the sensitivity of the data being collected and reported, CMS must ensure that only authorized personnel have access to data. Personnel are given access to the ESRD systems through the creation of user IDs and passwords within the QualityNet Identity Management System (QIMS); however, once within the system, the system determines the rights and privileges the personnel has over the data within the system.

The sole purpose the End Stage Renal Disease System (ESRD) System Access Request Form is to identify the individual's data access rights once within the ESRD system. This function and the associated data collection is currently being accomplished under ''Part B'' of the QualityNet Identity Management System Account Form (CMS–10267; OCN: 0938–1050). Once the ESRD System Access Form is approved, the QualityNet Identity Management System (QIMS) Account Form will be revised to remove Part B from the QIMS data collection. *Form Number:* CMS–10426 (OCN: 0938–New); *Frequency:* Yearly; *Affected Public:* Private Sector—Business or other for-profits. *Number of Respondents:* 25,000. *Number of Responses:* 25,000. *Total Annual Hours:* 6,250. (For policy questions regarding this collection contact Michelle Tucker at 410–786–0736. For all other issues call 410–786–1326.)

4. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Probable Fraud Measurement Pilot; *Use:* The Centers for Medicare & Medicaid Services (CMS) is seeking Office of Management and Budget (OMB) approval of the collections required for a probable fraud measurement pilot. The probable fraud measurement pilot would establish a baseline estimate of probable fraud in payments for home health care services in the fee-for-service Medicare program. CMS and its agents will collect information from home health agencies, the referring physicians and Medicare beneficiaries selected in a national random sample of home health claims. The pilot will rely on the information collected along with a summary of the service history of the HHA, the referring provider, and the beneficiary to estimate the percentage of total payments that are associated with probable fraud and the percentage of all claims that are associated with probable fraud for Medicare fee-for-service home health. *Form Number:* CMS–10406 (OCN: 0938–New); *Frequency:* Yearly; *Affected Public:* Individual and Private Sector—Business or other for-profits. *Number of Respondents:* 6,000. *Number of Responses:* 6,000. *Total Annual Hours:* 10,500. (For policy questions regarding this collection contact Kelly Gent at 410–786–0918. For all other issues call 410–786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by May 7, 2012:

1. *Electronically.* You may submit your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: March 1, 2012.

Martique Jones,

Director, Regulations Development Group, Division B, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2012–5439 Filed 3–5–12; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Tribal Consultation Meetings

AGENCY: Office of Head Start (OHS), Administration for Children and Families, HHS.

ACTION: Notice of meetings.

SUMMARY: Pursuant to the Improving Head Start for School Readiness Act of 2007, Public Law 110–134, notice is hereby given of one-day Tribal Consultation Sessions to be held between the Department of Health and Human Services, Administration for Children and Families, Office of Head Start leadership and the leadership of Tribal Governments operating Head Start (including Early Head Start) programs. The purpose of these Consultation Sessions is to discuss ways to better meet the needs of American Indian and Alaska Native children and their families, taking into consideration funding allocations, distribution formulas, and other issues affecting the delivery of Head Start services in their geographic locations [42 U.S.C. 9835, Section 640(l)(4)].

DATES: March 22 and April 3, 2012.

ADDRESSES: 2012 Office of Head Start Tribal Consultation Sessions will be held at the following locations: Thursday, March 22, 2012—Phoenix, Arizona—Sheraton Crescent Hotel, 2620 West Dunlap Avenue Phoenix, AZ 85021; Tuesday, April 3, 2012—Billings, Montana—Holiday Inn Grand Montana 5500 Midland Road, Billings, MT 59101.

FOR FURTHER INFORMATION CONTACT: Camille Loya, Acting Regional Program Manager Region XI, email *Camille.Loya@acf.hhs.gov* or phone (202) 401–5964. Additional information and online meeting registration is available at *http://www.headstartresourcecenter.org.*

SUPPLEMENTARY INFORMATION: The Department of Health and Human Services (HHS) announces Office of Head Start (OHS) Tribal Consultations with leaders of Tribal Governments operating Head Start (including Early Head Start) programs for each of the nine geographic regions of Head Start

where American Indian and Alaska Native (AI/AN) programs are located. We are convening the OHS Tribal Consultations in conjunction with other Tribal Leader events in order to minimize the financial and travel burden for participants. The sessions in Phoenix, Arizona, and Billings, Montana, are being held in conjunction with the HHS 2012 Regional Tribal Consultation Sessions. We will schedule additional consultations around the country for later in the year.

The agenda for the scheduled OHS Tribal Consultations will be organized around the statutory purposes of Head Start Tribal Consultations related to meeting the needs of AI/AN children and families, taking into consideration funding allocations, distribution formulas, and other issues affecting the delivery of Head Start services in their geographic locations. In addition, OHS will share actions taken and in progress to address the issues and concerns raised in 2011 OHS Tribal Consultations.

Tribal leaders and designated representatives interested in submitting written testimony or proposing specific agenda topics for these Consultation Sessions should contact Camille Loya at *Camille.Loya@acf.hhs.gov.* Proposals must be submitted at least three days in advance of the session and should include a brief description of the topic area, along with the name and contact information of the suggested presenter.

The Consultation Sessions will be conducted with elected or appointed leaders of Tribal Governments and their designated representatives [42 U.S.C.9835, Section 640(l)(4)(A)]. Designees must have a letter from the Tribal Government authorizing them to represent the tribe. The letter should be submitted at least three days in advance of the Consultation Session to Camille Loya at (202) 205–9721 (fax). Other representatives of tribal organizations and Native nonprofit organizations are welcome to attend as observers.

A detailed report of each Consultation Session will be prepared and made available within 90 days of the Consultation Session to all Tribal Governments receiving funds for Head Start and Early Head Start programs. Tribes wishing to submit written testimony for the report should send testimony to Camille Loya at *Camille.Loya@acf.hhs.gov* either prior to the Consultation Session or within 30 days after the meeting.

Oral testimony and comments from the Consultation Sessions will be summarized in each report without attribution, along with topics of concern and recommendations. Hotel and logistical information for all Consultation Sessions has been sent to tribal leaders via email and posted on the Head Start Resource Center Web site at *http://www.headstartresourcecenter.org.*

Dated: February 28, 2012.

Yvette Sanchez Fuentes,

Director, Office of Head Start.

[FR Doc. 2012–5438 Filed 3–5–12; 8:45 am]

BILLING CODE 4184–40–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0169]

Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: Under the Food and Drug Administration Modernization Act of 1997 (Modernization Act), the Food and Drug Administration (FDA) is required to report annually in the **Federal Register** on the status of postmarketing requirements and commitments required of, or agreed upon by, holders of approved drug and biological products. This notice is the Agency's report on the status of the studies and clinical trials that applicants have agreed to, or are required to, conduct.

FOR FURTHER INFORMATION CONTACT: Meg Pease-Fye, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4156, Silver Spring, MD 20993–0002, 301–796–0700; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Modernization Act

Section 130(a) of the Modernization Act (Pub. L. 105–115) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding a new provision requiring reports of certain postmarketing studies, including clinical trials, for human drug and biological products (section 506B of the FD&C Act (21 U.S.C. 356b)). Section 506B of the FD&C Act provides FDA with additional authority to monitor the progress of a postmarketing study or clinical trial that an applicant has been required to, or has agreed to, conduct by requiring the applicant to submit a report annually providing information on the status of the postmarketing study/clinical trial. This report must also include reasons, if any, for failure to complete the study/clinical trial. These studies and clinical trials are intended to further define the safety, efficacy, or optimal use of a product, and therefore play a vital role in fully characterizing the product.

Under the Modernization Act, commitments to conduct postmarketing studies or clinical trials included both studies/clinical trials that applicants agreed to conduct, as well as studies/clinical trials that applicants were required to conduct under FDA regulations.[1]

B. The Food and Drug Administration Amendments Act of 2007

On September 27, 2007, the President signed Public Law 110–85, the Food and Drug Administration Amendments Act of 2007 (FDAAA). Section 901, in Title IX of FDAAA, created a new section 505(o) of the FD&C Act authorizing FDA to require certain studies and clinical trials for human drug and biological products approved under section 505 of the FD&C Act or section 351 of the Public Health Service Act. Under FDAAA, FDA has been given additional authority to require applicants to conduct and report on postmarketing studies and clinical trials to assess a known serious risk, assess signals of serious risk, or identify an unexpected serious risk related to the use of a product. This new authority became effective on March 25, 2008. FDA may now take enforcement action against applicants who fail to conduct studies and clinical trials required under FDAAA, as well as studies and clinical trials required under FDA regulations (see sections 505(o)(1), 502(z), and 303(f)(4) of the FD&C Act (21 U.S.C. 355(o)(1), 352(z), and 333(f)(4))).

Although regulations implementing the Modernization Act postmarketing authorities use the term ''postmarketing commitment'' to refer to both required

[1] Before passage of the Food and Drug Administration Amendments Act of 2007 (FDAAA), FDA could require postmarketing studies and clinical trials under the following circumstances: To verify adn describe clinical benefit for a human drug approved in accordance with the accelerated approval provisions in section 506(b)(2)(A) of the FD&C Act (21 CFR 314.510 and 601.41); for a drug approved on the basis of animal efficacy data because human efficacy trials are not ethical or feasible (21 CFR 314.610(b)(1) and 601.91(b)(1)): and for marketed drugs that not adequately labeled for children under section 505B of the FD&C Act (Pediatric Research Equity Act (21 U.S.C. 355c; Pub. L. 108–155)).