1. Negotiate written agreements with the other agencies participating in the matching programs;

2. Obtain the Data Integrity Board approval of the match agreements;

3. Furnish detailed reports about matching programs to Congress and OMB;

4. Notify applicants and beneficiaries that the records are subject to matching; and,

5. Verify match findings before reducing, suspending, terminating, or denying an individual's benefits or payments.

This matching program meets the requirements of the Privacy Act of 1974, as amended.

Celeste Dade-Vinson,

Health Insurance Specialist, Centers for Medicare & Medicaid Services.

CMS Computer Match No. 2016–12

HHS COMPUTER MATCH NO. 1604

SSA COMPUTER MATCH NO. 1097–1899

NAME:

''Computer Matching Agreement between the Department of Health and Human Services, Centers for Medicare & Medicaid Services and the Social Security Administration for Determining Enrollment or Eligibility for Insurance Affordability Programs under the Patient Protection and Affordable Care Act''

SECURITY CLASSIFICATION:

Unclassified

PARTICIPATING AGENCIES:

Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS), and the Social Security Administration (SSA)

AUTHORITY FOR CONDUCTING MATCHING PROGRAM:

Sections 1411 and 1413 of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (collectively, the ACA) require the Secretary of HHS to establish a program for determining eligibility for certain state health subsidy programs, and certifications of Exemption; and authorize use of secure, electronic interfaces and an on-line system for the verification of eligibility.

PURPOSE(S) OF THE MATCHING PROGRAM:

The purpose of the Computer Matching Agreement (CMA) is to re-establish the terms, conditions, safeguards, and procedures under which SSA will disclose information to CMS in connection with the administration of state health subside programs under the ACA and its implementing regulations. SSA will provide data to CMS, and CMS will use SSA data needed to make initial eligibility determinations, eligibility redeterminations and renewal decisions, including appeal determinations, for state health subsidy programs and certifications of exemption. State health subsidy programs include:

1. Qualified Health Plan through an Exchange established under the ACA,

2. Advance payments of the premium tax credit and cost sharing reductions,

3. Medicaid,

4. Children's Health Insurance Program, and

5. Basic Health Program.

As set forth in the CMA, SSA will provide CMS the following information when relevant: (1) Social Security number (SSN) verifications, (2) a death indicator, (3) an indicator of a finding of disability by SSA under title II of the Social Security Act, (4) prisoner data, (5) monthly and annual Social Security benefit information under title II of the Social Security Act, (6) quarters of coverage, and (7) confirmation that an allegation of citizenship is consistent with SSA records.

DESCRIPTION OF RECORDS TO BE USED IN THE MATCHING PROGRAM:

The matching program will be conducted with data maintained by CMS in the Health Insurance Exchanges System (HIX), CMS System No. 09–70–0560, as amended, published at 78 FR 8538 (Feb. 6, 2013), 78 FR 32256 (May 29, 2013) and 78 FR 63211 (October 23, 2013).

The matching program will also be conducted with data maintained by SSA in the following SORs:

- Master Files of SSN Holders and SSN Applications, SSA/OEEAS, 60–0058, 75 FR 82121 (December 29, 2010), as amended 78 FR 40542 (July 5, 2013);
- Prisoner Update Processing System (PUPS), SSA/OPB, 60–0269, 64 FR 11076 (March 8, 1999), as amended 72 FR 69723 (December 10, 2007) and 78 FR 40542 (July 5, 2013);
- Master Beneficiary Record, SSA/ORSIS, 60–0090, 71 FR 1826 (January 11, 2006), as amended 72 FR 69723 (December 10, 2007) and 78 FR 40542 (July 5, 2013);
- Earnings Recording and Self-Employment Income System, SSA/OEEAS, 60–0059, 71 FR 1819(January 11, 2006), as amended 78 FR 40542 (July 5, 2013).

INCLUSIVE DATES OF THE MATCH:

The CMP will 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**, whichever is later. The matching program will continue for 18 months from the effective date and may be extended for an additional 12 months thereafter, if certain conditions are met.

[FR Doc. 2016–02527 Filed 2–8–16; 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 three 1-day Tribal Consultation Sessions to be held between the Department of Health and Human Services (HHS), Administration for Children and Families, OHS 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 7, 2016, from 1:30 p.m. to 5:00 p.m.

June 8, 2016, from 1:30 p.m. to 5:00 p.m.

August 8, 2016, from 1:00 p.m. to 5:00 p.m.

Locations:

- March 7, 2016—Hotel Albuquerque at Old Town, 800 Rio Grande Blvd. NW., Albuquerque, New Mexico 87104.
- June 8, 2016—Arlington Renaissance Capital View Hotel, 2800 South Potomac Avenue, Arlington, Virginia 22202.
- August 8, 2016—Northern Quest Resort & Casino, 100 North Hayford Road, Airway Heights, WA 99001.

FOR FURTHER INFORMATION CONTACT: Angie Godfrey, Regional Program Manager, Region XI/AIAN, Office of Head Start, email *Angie.Godfrey@acf.hhs.gov,* or phone (202) 205–5811. Additional information and online

meeting registration is available at: *http://eclkc.ohs.acf.hhs.gov/hslc/hs/calendar/tc2016.*

SUPPLEMENTARY INFORMATION: HHS announces OHS Tribal Consultations for leaders of Tribal Governments operating Head Start and Early Head Start programs. The agenda for the scheduled OHS Tribal Consultations in Albuquerque, New Mexico, Arlington, Virginia, and Spokane, Washington, will be organized around the statutory purposes of Head Start Tribal Consultations related to meeting the needs of American Indian and Alaska Native 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 the 2015 OHS Tribal Consultations.

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. Tribal Governments must submit the designee letter at least 3 days in advance of the Consultation Session to Angie Godfrey at *Angie.Godfrey@acf.hhs.gov.* 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 45 days of the Consultation Sessions 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 Angie Godfrey at *Angie.Godfrey@acf.hhs.gov* either prior to each Consultation Session or within 30 days after each meeting. OHS will summarize oral testimony and comments from the Consultation Session in each report without attribution, along with topics of concern and recommendations.

Dated: February 2, 2016.

Blanca E. Enriquez,

Director, Office of Head Start.

[FR Doc. 2016–02580 Filed 2–8–16; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2015–M–3256, FDA–2015–M–3257, FDA–2015–M–3258, FDA–2015–M–3376, FDA–2015–M–3377, FDA–2015–M–3516, FDA–2015–M–3516, FDA–2015–M–3519, FDA–2015–M–3520, FDA–2015–M–3521, FDA–2015–M–4013, FDA–2015–M–4014, FDA–2015–M–4015, FDA–2015–M–4016, FDA–2015–M–4017, FDA–2015–M–4018, FDA–2015–M–4069, FDA–2015–M–4343, FDA–2015–M–4344, FDA–2015–M–4434, FDA–2015–M–4728, FDA–2015–M–4947, and FDA–2015–M–4951]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the Agency's Division of Dockets Management.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket Nos. FDA–2015–M–3256, FDA–2015–M–3257, FDA–2015–M–3258, FDA–2015–M–3376, FDA–2015–M–3377, FDA–2015–M–3516, FDA–2015–M–3516, FDA–2015–M–3519, FDA–2015–M–3520, FDA–2015–M–3521, FDA–2015–M–4013, FDA–2015–M–4014, FDA–2015–M–4015, FDA–2015–M–4016, FDA–2015–M–4017, FDA–2015–M–4018, FDA–2015–M–4069, FDA–2015–M–4343, FDA–2015–M–4344, FDA–2015–M–4434, FDA–2015–M–4728, FDA–2015–M–4947, and FDA–2015–M–4951 for ''Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION''. The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this