application requirements for ANA's other funding opportunities. This proposed policy will be reflected in *Section IV.2. Content and Form of Application Submission—Project Description—Expected Outcomes—Objectives and V.1. Criteria—Outcomes Expected* in the I–LEAD FOA.

iii. Impact Indicator. ANA proposes applications for I–LEAD financial assistance include at least one impact indicator: a qualitative measure that defines factor(s) the project needs to benchmark and monitor. Impact indicators also provide the means for measuring and evaluating an I–LEAD project's progress and impact. This proposed policy will be reflected in the *Section IV.2. Content and Form of Application Submission—Project Description—Expected Outcomes—Impact* in the I–LEAD FOA.

e. Project Budget and Budget Justification. I–LEAD applicants are required to attend ANA's annual grantee meeting. We propose to add a new requirement of attendance for an additional day to convene with I–LEAD projects funded by ANA and the youth involved in project implementation. This proposed policy will be reflected in *Section IV.2. Content and Form of Application Submission—Project Description—Project Budget and Budget Justification* in the I–LEAD FOA and will also reflect suggested travel costs increased by $500 per region for additional estimated lodging and per diem.

f. Review Criteria—

i. Elimination of Bonus Points. ANA proposes to remove the bonus points that were authorized in FY 2016 I–LEAD FOAs because our experience with the prior year's application review demonstrated the allocation of up to 5 bonus points for letters of support from youth is not necessary to ensure applications reflect support from youth involved in the development of the project proposal as well as in project implementation. The proposed application point allocation reflecting the discontinued use of bonus points is found at *Section V.1. Criteria* of the I–LEAD FOA.

ii. Allocation of points across I–LEAD application evaluation criteria. ANA proposes to modify the point allocation across I–LEAD application review criteria to account for the proposed elimination of bonus points as well as the proposed OWP application requirement. We propose, beginning in FY 2017, the following evaluation criteria point allocations: Needs for Assistance up to 10 points; Outcomes Expected up to 25 points; Approach up to 35 points; OWP up to 20 points; and the Budget and Budget Justification up to10 points. The proposed modification to the point allocation can be found at *Section V.1. Criteria* for the I–LEAD FOA.

Statutory Authority: Section 814 of the Native American Programs Act of 1974 (NAPA), as amended.

Kimberly Romine,

Deputy Commissioner, Administration for Native Americans.

[FR Doc. 2017–01418 Filed 1–19–17; 8:45 am]

BILLING CODE 4184–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Project: Performance Reporting for the Tribal Maternal, Infant, and Early Childhood Home Visiting Grant Program.

Title: Tribal Maternal, Infant, and Early Childhood Home Visiting Program Performance Reporting Form 2.

OMB No.: New Collection.

Description: Social Security Act, Title V, Section 511 (42 U.S.C. 711), as added by § 2951 of the Patient Protection and Affordable Care Act (Pub. L. 111–148), created the Maternal, Infant, and Early Childhood Home Visiting Program (MIECHV) and authorized the Secretary of HHS (in Section 511(h)(2)(A)) 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 set aside 3 percent of the total MIECHV program appropriation (authorized in Section 511(j)) for grants to tribal entities. The implementation of the program is a collaborative endeavor between Health Resources Services Administration (HRSA) and the Administration for Children and Families (ACF). HRSA administers the State MIECHV program while ACF administers the Tribal MIECHV program. The goal of the Tribal MIECHV program is to support the development of happy, healthy, and successful American Indian and Alaska Native children and families through a coordinated home visiting system. Tribal MIECHV grants, to the greatest extent practicable, are to be consistent with the requirements of the MIECHV grants to states and jurisdictions (authorized in Section 511(c)), and include conducting a needs assessment and establishing quantifiable, measurable benchmarks.

Specifically, the MIECHV legislation requires that State and Tribal MIECHV grantees collect data to measure improvements for eligible families in six specified areas (referred to as ''benchmark areas'') that encompass the major goals for the program and are listed below:

1. Improved maternal and newborn health;
2. Prevention of child injuries, child abuse, neglect, or maltreatment, and reduction in emergency department visits;
3. Improvement in school readiness and achievement;
4. Reduction in crime or domestic violence;
5. Improvement in family economic self-sufficiency;
6. Improvement in the coordination and referrals for other community resources and supports.

Tribal Home Visiting (HV) Form 2—Tribal Grantees Performance Reporting

The proposed Tribal HV Form 2 will be used by two new cohorts of Tribal MIECHV grantees that were funded in FY2016 to report their benchmark performance measures. As stipulated in the MIECHV legislation, the Tribal MIECHV grantees, like their State counterparts, must meet the required reporting of benchmark areas. Tribal MIECHV grantees are required to propose a plan for meeting the benchmark requirements specified in the legislation and must report on improvement at the end of Year 4 and Year 5 of their 5-year grants, (*i.e.* after 3 years of implementation and at the end of their 5-year grant).

The Tribal HV Form 2 will be used by Tribal MIECHV grantees beginning in October 2018 pending OMB approval. The Tribal HV Form 2 is new to the MIECHV Program information system and is remotely similar to the currently-approved Tribal HV Form 3 (OMB #0915–0357). The creation of Tribal HV Form 2 is due to the added level of specificity and revised performance reporting requirements for grantees to report benchmarks data.

Specifically, ACF will use the proposed Tribal HV Form 2 to:

- Track and improve the quality of benchmark measure data submitted by the Tribal grantees;
- Improve program monitoring and oversight;
- Improve rigorous data analyses that help to assess the effectiveness of the programs and enable ACF to better monitor projects; and

• Ensure adequate and timely reporting of program data to relevant federal agencies and stakeholders including the Congress, and members of the public.

Tribal HV Form 2 will provide a template for Tribal MIECHV grantees to report data on their progress under the six benchmark areas as stipulated in legislation.

Respondents: Tribal Maternal, Infant, and Early Childhood Home Visiting Program Grantees.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Tribal Maternal, Infant, and Early Childhood Home Visiting Performance Reporting Form	20	1	500	10,000

Estimated Total Annual Burden Hours: 10,000.

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 Planning, Research and Evaluation, 330 C St. SW., Washington, DC 20201, Attn: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@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.

Mary Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2017–01276 Filed 1–19–17; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–P–0377]

Determination That ACTHAR GEL SYNTHETIC (Seractide Acetate) Injection, 80 Units/Milliliter and 40 Units/Milliliter, Was Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) has determined that ACTHAR GEL SYNTHETIC (seractide acetate) injection, 80 units/milliliter (mL) and 40 units/mL, was withdrawn from sale for reasons of safety or effectiveness. The Agency will not accept or approve abbreviated new drug applications (ANDAs) for seractide acetate injection, 80 units/mL and 40 units/mL.

FOR FURTHER INFORMATION CONTACT: David E. Markert, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6222, Silver Spring, MD 20993–0002, 301–796–0752.

SUPPLEMENTARY INFORMATION:

I. Background

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (21 CFR 314.161). FDA may not approve an ANDA that does not refer to a listed drug.

ACTHAR GEL SYNTHETIC (seractide acetate) injection, 80 units/mL and 40 units/mL was the subject of NDA 017861, which was held by Armour Pharmaceutical Co. (Armour), and initially approved on February 21, 1978. ACTHAR GEL SYNTHETIC is indicated for diagnostic testing of adrenocortical function. The labeling also provides that ACTHAR GEL SYNTHETIC may be employed in the following disorders:

Endocrine Disorders: Nonsuppurative thyroiditis; Hypercalcemia associated with cancer.

Nervous System Diseases: Acute exacerbations of multiple sclerosis.

Rheumatic Disorders: As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: Psoriatic arthritis; rheumatoid arthritis, including juvenile