ANA plans to modify the description of program purpose for the SEDS–AK FOA to expand the program areas of interest beyond governance. In addition, ANA wants to provide a competitive advantage for smaller Alaska Native villages or organizations that have never received ANA funding. Therefore, the FOA will state that reviewers may add up to 10 bonus points in the scoring criteria if an eligible entity that has never received an ANA award. ANA staff will confirm during the objective review process whether or not an applicant organization for SEDS–AK has received a past ANA award.

a. *Changes to EMI FOA*—Section 803C of NAPA, 42 U.S.C. 2991b–3. In accordance with 42 U.S.C. 2991b–3(c)(7), applicants for an EMI grant must provide a certification that the organization has not less than 3 years of experience in operating and administering a Native American language survival school, a Native American language nest, or any other educational program in which instruction is conducted in a Native American language. Previously, this requirement only applied to Native American language survival schools. ANA will now require all applicants for EMI to provide a certification of operation of not less than 3 years.

b. *Clarification to ERE FOA*—Section 803 of NAPA, 42 U.S.C. 2991b.

i. Section 803(d)(3) of NAPA (42 U.S.C. 2991b(d)(3)) permits Federal funds to be used as cost sharing or matching funds for an ERE project, as long as they are not provided from other ANA grants. Therefore, ANA will add this clarification in the ERE FOA. Before using Federal grant funds as matching funds, grantees must make sure that the authorizing statute for the matching Federal grant funds specifically allows its grant funds to be used as cost share or matching funds.

ii. ANA will also permit entities to apply for ERE grants even if they do not own land. There is no requirement within the provisions for ERE under NAPA that require the eligible entity to own land. Applications will be evaluated in accordance with the evaluation criteria in the FOA, including ensuring the purpose of the ERE program will be met.

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

Jean Hovland,

Commissioner, Administration for Native Americans, Administration for Children and Families.

[FR Doc. 2019–27916 Filed 12–26–19; 8:45 am]

BILLING CODE 4184–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–2434]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Formal Meetings Between the Food and Drug Administration and Sponsors and Applicants of Prescription Drug User Fee Act Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by January 27, 2020.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0429. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Formal Meetings Between FDA and Sponsors and Applicants of Prescription Drug User Fee Act Products

OMB Control Number 0910–0429—Reinstatement

This information collection supports implementation of the Prescription Drug User Fee Amendments (PDUFA) of the FDA Reauthorization Act of 2017 (FDARA). Consistent with Agency regulations and provisions found in our ''Reauthorization Performance Goals And Procedures: Fiscal Years 2018 Through 2022,'' we have established procedural guidance pertaining to formal meetings between FDA and sponsors or applicants of certain drug or biological drug products regulated by the Center for Drug Evaluation (CDER) and Research and the Center for Biologics Evaluation and Research (CBER). Because these meetings often represent critical points in the regulatory process, we intend these recommendations to facilitate the timely and effective scheduling of such meetings, as well as ensure their efficiency and appropriate documentation.

While FDA regulations in 21 CFR 10.65, 312.47, 314.50, and 314.102 describe general considerations and set forth certain information collection elements pertaining to meetings with FDA, the guidance document entitled, ''Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products,'' discusses specific topics for sponsors of PDUFA products such as types of meetings, meeting formats, meetings requests, FDA response, and meeting packages. The guidance recommendations do not apply to abbreviated new drug applications, applications for biosimilar biological products, or submissions for medical devices. Issued consistent with our Good Guidance Practice regulations in 21 CFR 10.115, we originally developed the guidance in 1999 and it has since undergone various revisions to reflect reauthorization of relevant user fee legislation. The guidance explains our recommendations with regard to PDUFA meetings and that the following elements be included in a meeting request to FDA:

- Information identifying and describing the product;
- the type of meeting being requested; a brief statement of the purpose of the meeting;
- a list of objectives and expected outcomes from the meeting;
- a preliminary proposed agenda; a draft list of questions to be raised at the meeting;
- a list of individuals who will represent the sponsor or applicant at the meeting;
- a list of Agency staff requested to be in attendance;
- the approximate date that the information package will be sent to the Agency;
- and suggested dates and times for the meeting.

We use the information to determine the purpose of the meeting and to

arrange for scheduling and participation as appropriate.

Similarly, the guidance explains and discusses the preparation of an ''information package'' and recommends that it include the following information:

- Identifying information about the underlying product;
- a brief statement of the purpose of the meeting; a list of objectives and expected outcomes of the meeting;
- a proposed agenda for the meeting;
- a list of specific questions to be addressed at the meeting;
- a summary of clinical data that will be discussed (as appropriate);
- a summary of preclinical data that will be discussed (as appropriate); and
- chemistry, manufacturing, and controls information that may be discussed (as appropriate).

The information package enables us to prepare for the meeting and allows appropriate time for reviewing relevant product data. Although FDA reviews similar information in the meeting request, the information package should provide updated data reflecting the most current and accurate information available to the sponsor or applicant.

In the **Federal Register** of July 11, 2018 (83 FR 32130) we published a 60-day notice under the Paperwork Reduction Act of 1995 (PRA) requesting public comment on the proposed collection of information associated with meeting requests under PDUFA. No comments were received in response to the PRA notice. Separately, in the **Federal Register** (December 29, 2017; 82 FR 61763), we published a notice of availability announcing a 2017 revised draft version of the subject guidance, ultimately intending it to replace the current 2009 version. In the December 2017 notice of availability, the 2009 version was inadvertently withdrawn and the associated information collection discontinued. Accordingly, we are requesting reinstatement of the information collection. Although the associated guidance is currently being revised to reflect 2018–2022 PDUFA reauthorization goals and is being issued consistent with our Good Guidance Practice Regulation at 21 CFR 10.115, no changes have been made to the information collection elements recommended, nor have we modified the burden estimate we ascribe to the related activities.

We therefore estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Guidance recommendations	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Meeting Requests:					
CDER	1,319	2.31	3,058	10	30,580
CBER	301	1.21	363	10	3,630
Subtotal					34,210
Information Packages:					
CDER	1,149	2.19	2,522	18	45,396
CBER	187	1.12	210	18	3,780
Subtotal					49,176
Total					83,386

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimate reflects an overall increase since the previous OMB approval. We attribute this adjustment to an increase in the number of PDUFA-related meeting requests and information packages we have received over the last few years.

Based on Agency data, we estimate 1,319 sponsors and applicants (respondents) request 3,058 formal meetings with CDER annually, and 301 respondents request 363 formal meetings with CBER annually regarding the development and review of a PDUFA product. The hours per response, which is the estimated number of hours that a respondent spends preparing the information to be submitted with a meeting request in accordance with the guidance, is estimated to be 10 hours. We expect it takes this amount of time to gather and copy brief statements about the product as well as a description of the purpose and details of the meeting.

Also consistent with Agency data, we estimate 1,149 respondents submitted 2,522 information packages to CDER annually, and 187 respondents submitted 210 information packages to CBER annually, prior to a formal meeting regarding the development and review of a PDUFA product. We estimate 18 hours is needed to prepare the information package in accordance with the guidance.

Dated: December 10, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–27835 Filed 12–26–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program: List of Petitions Received

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HRSA is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by Section 2112(b)(2) of the Public Health Service (PHS) Act, as amended. While the Secretary of HHS is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility