of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002 or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Shanthi Marur, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2369, Silver Spring, MD 20993–0002, 240–402–6373; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Evaluating Cancer Drugs in Patients with Central Nervous System Metastases.'' This draft guidance provides recommendations for sponsors designing clinical trials of drugs and biological products regulated by CDER and CBER that are intended to support product labeling describing the antitumor activity in patients with central nervous system (CNS) metastases from solid tumors originating outside the CNS. Specifically, the draft guidance includes recommendations regarding the patient population, available therapy, prior therapies, assessment of CNS disease, study endpoints, and leptomeningeal disease. The draft guidance describes that CNS metastases should be evaluated in the context of the entire disease burden and discusses how treatment effects may be described in drug labeling. The recommendations pertain to clinical trials for systemic anticancer drugs where patients with CNS metastases are included in the study population. These recommendations are also applicable to trials conducted exclusively in patients with CNS metastases.

CNS metastases are associated with significant morbidity and mortality and development of therapeutic products for patients with CNS metastases is needed. FDA has participated in efforts to facilitate drug development for patients with CNS metastases including a March 2019 ''Workshop on Product Development for CNS Metastases''. Stakeholders at this meeting stated there is a need for further FDA guidance on specific topics including identifying optimal study endpoints. Study design challenges for CNS metastases include uncertainty regarding optimal endpoints, lack of standardized response assessments, understanding how CNS metastases are evaluated in the context of the entire burden of metastatic disease to characterize a drug's potential benefit (*e.g.,* timing of CNS radiographic assessments relative to other sites of metastases), and interpreting radiographic response in the setting of recent radiation therapy or surgery. This draft guidance is intended to provide recommendations on these study design challenges.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Evaluating Cancer Drugs in Patients with Central Nervous System Metastases.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; the collections of information in 21 CFR part 601 have been approved under 0910–0338; and the collections of information in 21 CFR 201.56 and 201.57 have been approved under OMB control number 0910–0572.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.regulations.gov.*

Dated: August 24, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–18894 Filed 8–26–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Solicitation of Nominations for Membership To Serve on Tribal Advisory Council

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

ACTION: Notice.

SUMMARY: HRSA is seeking additional nominations of qualified tribal officials as candidates for consideration for appointment as voluntary delegate members of the HRSA Tribal Advisory Council (TAC), which is being established. Specifically, HRSA requests submissions of nominations of qualified tribal officials from the Indian Health Service (IHS) geographic areas of: Alaska; Albuquerque; Billings; Navajo; Phoenix; and Tucson. Nominations for membership must be received on or before September 30, 2020. This will allow tribes and tribal serving organizations from the IHS geographic areas noted above, the additional time needed to identify qualified tribal officials as candidates and submit comprehensive nomination packages.

FOR FURTHER INFORMATION CONTACT: CAPT Elijah K. Martin, Jr. EdD, MPH, Manager, Tribal Health Affairs, Office of Health Equity, HRSA, 5600 Fishers Lane, Room 13N44, Rockville, Maryland

20857, 301–443–7526, *aianhealth@hrsa.gov.*

SUPPLEMENTARY INFORMATION: The HRSA TAC will be established to engage in regular and meaningful collaboration and consultation with tribal officials on policies that have tribal implications and substantial direct effect on Indian tribes. HRSA, an agency of the U.S. Department of Health and Human Services (HHS), is the primary federal agency for improving health care to people who are geographically isolated, and/or economically or medically vulnerable. This includes people living with HIV/AIDS; pregnant women, mothers, and their families; and those otherwise unable to access high-quality health care. HRSA supports the training of health professionals, the distribution of providers to areas where they are needed most, and improvements in health care delivery. HRSA also oversees organ, bone marrow, and cord blood donation. It also oversees the National Vaccine Injury Compensation Program which can provide compensation to individuals in the rare cases that they are harmed by certain covered vaccinations and maintains databases that flag providers with a record of health care malpractice, waste, fraud, and abuse for federal, state, and local use.

The HRSA TAC will be the vehicle for acquiring a broad range of tribal views, determining the impact of HRSA programs on the American Indian and Alaska Natives health systems and population, developing innovative approaches to deliver health care, and assisting with effective tribal consultation. The HRSA TAC will hold one meeting each calendar year, or at the discretion of HRSA in consultation with the Chair. These meetings may be held in-person or virtually. The HRSA TAC will support, not supplant, any other government-to-government consultation activities that HRSA undertakes. In addition to assisting HRSA in the planning and coordination of tribal consultation sessions, the HRSA TAC will advise HRSA regarding the government-togovernment consultation process and will help ensure that HRSA activities and policies that impact Indian country are brought to the attention of all tribal leaders.

Nominations: A previous notice regarding the HRSA TAC was published in the **Federal Register** on February 6, 2020. The deadline for submissions was extended to July 6, 2020, and while HRSA received additional nomination packets, it did not receive a sufficient number of nomination packets to consider for each of the 12 vacant positions. HRSA is requesting nominations of tribal officials to serve as HRSA TAC delegate members to fill up to 12 voluntary positions on the HRSA TAC; one authorized tribal representative (and one designated alternate) from each of the Indian Health Service geographic areas. HRSA continues to seek additional qualified nominees, specifically from eligible tribal officials from the IHS geographic areas of: Alaska; Albuquerque; Billings; Navajo; Phoenix; and Tucson. The HRSA Administrator will appoint HRSA TAC delegate members with the expertise needed to fulfill the duties of the Advisory Council. Nominees will be considered in the following priority order:

1. Tribal president, chairperson, or governor;
2. Tribal vice president, vice-chairperson, or lieutenant governor;
3. Elected or appointed tribal official; and
4. Designated tribal official.

Interested applicants may self-nominate or be nominated by another individual or organization.

Individuals selected for appointment to the HRSA TAC will be invited to serve terms of up to 2 years. Appointed delegate members will receive per diem and travel expenses incurred for attending HRSA TAC meetings and/or conducting other authorized and approved business on behalf of the HRSA TAC.

The following information must be included in the package of materials submitted for each individual nominated for consideration: (1) Name of the nominee, a description of the interests the nominee would represent, and a description of the nominee's experience and interest in American Indian and Alaska Native access to health care; (2) evidence that the nominee is a duly elected or appointed tribal leader or tribal officer, or has been designated with authority to act on behalf of the duly elected or appointed tribal leader or officer, and is authorized to represent a tribal government; (3) a written commitment from the nominee that they will actively participate in good faith in HRSA TAC meetings; and (4) a current copy of the nominee's curriculum vitae. Nomination packages may be submitted directly by the individual being nominated or by the person/organization recommending the candidate.

HHS endeavors to ensure that the membership of the HRSA TAC is fairly balanced in terms of points of view represented and that individuals from a broad representation of geographic areas, gender, and ethnic and minority groups, as well as individuals with disabilities, are considered for membership. Appointments shall be made without discrimination on the basis of age, ethnicity, gender, sexual orientation, or cultural, religious, or socioeconomic status.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2020–18865 Filed 8–26–20; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Be the Match® Patient Support Center Survey; OMB No. 0906–0004—Revision

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

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30 day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than September 28, 2020.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION: