

tribes.” Finally, ACF recently issued the *ACF Principles for Working with Federally Recognized Indian Tribes*, effective October 20, 2016, that affirmed ACF’s commitment to receive input from elected tribal representatives as well as “to otherwise ensure human services coordination around issues affecting AI/AN populations.”

Consistent with the above affirmative statements of the value of feedback from AI/AN partners and stakeholders, ACF is requesting information from AI/AN tribes, tribal organizations, and stakeholders (including grantees). The purpose is to identify issues and challenges facing AI/AN populations as well as to inform ACF of tribes’ and tribal organizations’ recommendations, promising practices, and innovations to address the needs of AI/AN children, youth, families, and communities. This information may, in turn, be used by ACF in the development of future rulemaking and technical assistance, formation of legislative proposals and research agendas, and strategic planning in consultation with tribes.

II. Request for Information

As President Obama stated in his Presidential Proclamation—National Native American Heritage Month (2016):

Let us continue to build on the advancements we have made, because enduring progress will depend on our dedication to honoring our trust and treaty responsibilities. With sustained effort and unwavering optimism, we can ensure a vibrant and resilient Indian Country filled with possibility and prosperity.

In this RFI, we seek feedback and recommendations related to how ACF partners with tribes and how to make progress in the future. The following questions are not exhaustive, and we encourage commenters to provide any additional information they believe relevant to ACF’s work with and on behalf of American Indians and Alaska Natives. You may provide general comments, respond to all questions posed in section II of this RFI, or respond to one or more questions. If you respond to any of the questions in section II, please identify the number that corresponds to the question(s) you are responding to. Include our agency name and the docket number on all submissions. Please do not include confidential information, or otherwise sensitive or protected information with your responses.

(1) Are there challenges to AI/AN tribes and tribal organizations posed by non-federal match or cost sharing requirements in any applicable ACF programs? Please be specific as to the program or programs you are referring to

as well as provide as much detail as possible in describing challenges or difficulties posed and any specific recommendations you wish to provide.

(2) Are there challenges to AI/AN tribes and tribal organizations posed by administrative cost caps required under some ACF grant programs? Please be specific as to the program or programs you are referring to as well as provide as much detail as possible in describing challenges or difficulties posed and any specific recommendations you wish to provide.

(3) Are there instances for which you believe waiver authority, additional waiver authority allowed under block grants, would benefit tribes under any ACF programs? Please be specific as to the program or programs you are referring to as well as provide as much detail as possible in describing challenges or difficulties posed and any specific recommendations you wish to provide.

(4) For ACF programs that currently have waiver authority for tribes, do you recommend ACF streamline the processes under which AI/AN tribes and tribal organizations apply for or request waivers of statutory or regulatory requirements across ACF grant programs? Please be specific as to the program or programs you are referring to as well as provide as much detail as possible in describing where you believe additional streamlining is needed, along with any specific recommendations you wish to provide.

(5) Are there regulatory or administrative barriers that present challenges to AI/AN tribes and tribal organizations in the implementation of ACF grant programs? Please be specific about what those regulatory or administrative barriers are as well as recommendations for addressing them.

(6) Can you identify practices, policies, and procedures in ACF or elsewhere that are particularly effective in meeting the needs of AI/AN tribes, tribal organizations, families, and communities? Please be specific as to the program or programs you are referring to as well as provide as much detail as possible in describing effective and responsive practices, policies, and procedures.

(7) Related to data, what would you recommend ACF either collect (if it does not already) or analyze that would be most useful to inform our work with AI/AN tribes and tribal organizations? Please be specific and provide as much detail as possible.

(8) Do you have recommendations for how ACF could better share data related to AI/AN grantee program performance, outcomes, and sustainability? Please be

specific, including recommended use of technological or other means of data sharing.

(9) Are there elements of the application process that could potentially discourage AI/AN tribes or organizations from applying for ACF grants? If so, please specify what those elements are and explain why those elements could potentially discourage prospective AI/AN applicants and any recommendations for addressing such barriers.

III. Response to Comments

Because of the large number of public comments we normally receive, we are not able to acknowledge or respond to them individually. However, comments will be accepted on this RFI through <https://www.Regulations.gov> where you will be able to track your own comments and view other comments we receive.

Dated: January 3, 2017.

Mark H. Greenberg

Acting Assistant Secretary for Children and Families.

Dated: January 3, 2017.

Stacey Ecoffey,

Acting Deputy Assistant Secretary for Native American Affairs and Acting Commissioner Administration for Native Americans.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-2537]

Submission of Quality Metrics Data; Revised Draft Guidance for Industry; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for the notice of revised draft guidance availability that appeared in the **Federal Register** of November 25, 2016. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the notice of revised draft guidance availability published on November 25, 2016 (81 FR 85226). Submit either electronic or written comments by March 27, 2017.

ADDRESSES: You may submit comments by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://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 <https://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 Submissions

Submit written submissions in the following ways:

- **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 No. FDA-2015-D-2537 for "Submission of Quality Metrics Data; Revised Draft Guidance for Industry." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://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 <https://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 information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

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(s), found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Tara Gooen Bizjak, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2109, Silver Spring, MD 20993-0002, 301-796-3257 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: In the **Federal Register** of November 25, 2016, FDA published a notice of revised draft guidance availability with a 60-day comment period. Comments on the notice of revised draft guidance availability will inform FDA's development and proposed implementation of a voluntary phase of the quality metrics program.

FDA is extending the comment period for an additional 60 days, until March 27, 2017. The Agency believes that a 60-day extension of the comment period for

the notice of revised draft guidance availability will provide adequate time for interested persons to submit comments without significantly delaying Agency decision making on these important issues.

Dated: January 3, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0001]

Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Circulatory System Devices Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will be held on February 23, 2017, from 8 a.m. to 6 p.m.

ADDRESSES: Hilton Washington, DC/North, Salons A, B, C and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's phone number is 301-977-8900. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FOR FURTHER INFORMATION CONTACT: Evella Washington, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G640, Silver Spring, MD 20993-0002, Evella.Washington@fda.hhs.gov, 301-796-6683, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/>