

state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any “trade secret or any commercial or financial information which . . . is privileged or confidential”—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled “Confidential,” and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. See FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on the public FTC website—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment from the FTC website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before November 26, 2019. For information on the Commission’s privacy policy, including routine uses permitted by the Privacy Act, see <https://www.ftc.gov/site-information/privacy-policy>.

Heather Hipsley,

Deputy General Counsel.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA Number: 93.612]

Announcement of the Intent To Award an Emergency Single-Source Grant

AGENCY: Administration for Native Americans (ANA), Administration for Children and Families (ACF), Department of Health and Human Services (HHS).

ACTION: Notice of intent to issue an emergency single-source award to 500 Sails, Inc. in Saipan, Commonwealth of the Northern Mariana Islands.

SUMMARY: The ACF, ANA, Division of Program Operations (DPO) intends to award a grant of \$106,638 to 500 Sails, Inc. in Saipan, Commonwealth of the Northern Mariana Islands. The purpose of the award is to support restoration of culturally significant sites and a digital storytelling project after the devastating effects of Typhoon Yutu in October, 2018.

DATES: The intended period of performance for this award is 09/30/2019 through 09/29/2020.

FOR FURTHER INFORMATION CONTACT: Carmelia Strickland, Director, Division of Program Operations, Administration for Native Americans, 330 C Street SW, Switzer Bldg. 4115, Washington, DC 20201. Telephone: 202–401–6741; Email: Carmelia.Strickland@acf.hhs.gov.

SUPPLEMENTARY INFORMATION: An emergency declaration by President Donald Trump was issued for the Commonwealth of the Northern Mariana Islands (CNMI) on October 27, 2018. In the spring of 2019, ANA’s Pacific Basin Training and Technical Assistance Center performed an assessment of community needs that were not addressed by other federal agencies in response to the catastrophic storm. A report was prepared for ANA with a series of projects aiming to reduce the post-traumatic stress of 200 Chamorro and Carolinian community members through storytelling, and to repair and/or restore six culturally significant sites and two ANA project sites. Currently, the CNMI government is burdened with the reconstruction of homes and governmental infrastructure that were damaged by Typhoon Yutu. The award will be carried out by 500 Sails, Inc., a non-profit organization located in Saipan, CNMI, to serve as the grants administrator and project coordinator for the proposed projects. 500 Sails, Inc.

is a current ANA grantee with an ending 3-year project period and has successfully administered an ANA award. They have the organizational capacity, including accounting and data management, as well as qualified staff in place. In addition, the organization has the community connections, partnerships, and experience to successfully implement the award. The Board of Directors for 500 Sails, Inc has included a board resolution in support of the application and the 9 proposed projects. The activities within the project are designed to incorporate cultural ways of supporting the recovery after Typhoon Yutu. The proposed projects include the cultural component that no other federal agency could provide, and it allows for a holistic approach to the recovery. Most of the projects include volunteer opportunities for community members to help in the rebuilding of their community. The application will be awarded in compliance with HHS policy for emergency awards, including after an objective review has been conducted.

Statutory Authority: Section 803(a) of the Native American Programs Act of 1974 (NAPA), 42 U.S.C. 2991b.

Elizabeth Leo,

Senior Grants Policy Specialist, Division of Grants Policy, Office of Administration.

[FR Doc. 2019–20996 Filed 9–24–19; 11:15 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–6294]

Changes to Existing Medical Software Policies Resulting From Section 3060 of the 21st Century Cures Act; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled “Changes to Existing Medical Software Policies Resulting From Section 3060 of the 21st Century Cures Act.” This guidance provides clarity on FDA’s current thinking regarding changes made by the 21st Century Cures Act (Cures Act) to the definition of a medical device and the resulting effect on guidances related to medical device software.