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 Hippsley,

Deputy General Counsel.

[FR Doc. 2019–20967 Filed 9–26–19; 8:45 am]

BILLING CODE 6750–01–P

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, Commonweath 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]

BILLING CODE 4184–34–P

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.

DATES: The announcement of the guidance is published in the **Federal Register** on September 27, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

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/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2017–D–6294 for ''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.'' 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 Dockets Management Staff 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 Dockets Management Staff. 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: *https://www.gpo.gov/fdsys/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)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, 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 request.

FOR FURTHER INFORMATION CONTACT: Bakul Patel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5458, Silver Spring, MD 20993–0002, 301–796–5528; 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, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has long regulated software that meets the definition of a device. Section 3060(a) of the Cures Act, enacted on December 13, 2016 (Pub. L. 114–255), amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to exclude certain software functions from the definition of device under section 201(h) of the FD&C Act (21 U.S.C. 321(h)). The software functions that are removed from the definition of device are described in section 520(o)(1) of the FD&C Act (21 U.S.C. 360j(o)(1)), and the intended uses of such software functions can be summarized as follows: (1) For administrative support of a healthcare facility, (2) for maintaining or encouraging a healthy lifestyle, (3) to serve as electronic patient records, (4) for transferring, storing, converting formats, or displaying data, or (5) providing certain types of clinical decision support to a healthcare provider unless interpreting or analyzing a clinical test or other device data.

This guidance provides FDA's current thinking regarding the amended device definition and the resulting effect the amended definition has on published FDA guidance, including the policies expressed in guidance about mobile medical applications; medical device data systems used for the electronic transfer, storage, display, or conversion of medical device data; medical image storage devices, used to store or retrieve medical images electronically; and general wellness products. This guidance focuses on the first four categories of software functions that are excluded from the device definition. FDA will address the fifth category in a separate guidance. Elsewhere in this

issue of the **Federal Register**, FDA is announcing the availability of the draft guidance entitled ''Clinical Decision Support Software'' to provide clarification of its interpretation of section 520(o)(1)(E) of the FD&C Act, which describes certain software functions intended to provide decision support for the diagnosis, treatment, prevention, cure, or mitigation of disease or other conditions. Section 520(o)(2) of the FD&C Act describes the regulation of a product with multiple functions, including at least one device function and at least one software function that is not a device. FDA intends to provide recommendations on the regulation of such products with multifunctionality in a separate guidance document.

FDA considered comments received on the draft guidance that appeared in the **Federal Register** of December 8, 2017 (82 FR 57991). FDA revised the guidance as appropriate in response to the comments. FDA has provided additional clarity that hardware intended to transfer, store, convert formats, and display medical device data and results remain devices, while software functions intended to transfer, store, convert formats, or display data are no longer devices if they meet the definition in 520(o)(1)(D) of the FD&C Act. The examples included in the draft of this guidance that described alarms, alerts, or flags have been removed from this guidance, because they are not excluded from the definition of device under section 520(o)(1)(D) of the FD&C Act in that these functions involve analysis or interpretation of laboratory test or other device data and results. These functions are addressed in section 520(o)(1)(E) of the FD&C Act, the regulation of which will be described in the separate ''Clinical Decision Support Software'' guidance document.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act.'' 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. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics.* Persons unable to download an electronic copy of ''Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 17030 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. 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 the following FDA regulations have been approved by OMB as listed in the following table:

21 CFR part	Topic	OMB Control No.
807, subparts A through D	Establishment Registration And Device Listing	0910–0625
807, subpart E	Premarket Notification	0910–0120
800, 801, and 809	Medical Device Labeling Regulations	0910–0485
803	Medical Devices; Medical Device Reporting; Manufacturer Reporting, Importer Reporting, User Facility Reporting, Distributor Reporting.	0910–0437
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation	0910–0073

Dated: September 23, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–21001 Filed 9–26–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–6569]

Clinical Decision Support Software; Draft 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 the draft guidance entitled ''Clinical Decision Support Software.'' This guidance clarifies the types of clinical decision support (CDS) functions that do not meet the definition of a device as amended by the 21st Century Cures Act (Cures Act). This guidance describes a risk-based approach for regulatory oversight of CDS software functions that remain devices using the categories defined by the International Medical Device Regulators Forum (IMDRF) final document entitled ''Software as a Medical Device: Possible Framework for Risk Categorization and Corresponding Considerations.'' The guidance also provides clarity on the types of CDS software functions on which FDA intends to focus its regulatory oversight for health care providers, patients, and caregivers. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by December 26, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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