

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Announcement of Expansion Supplement Grant Awards

AGENCY: Administration for Native Americans, ACF, HHS.

ACTION: Notice to 10 Expansion Supplement Awards to implement the First Lady's *Let's Move! in Indian Country* (LMIC) initiative.

CFDA#: 93.612.

Statutory Authority: The awards will be made pursuant to Section 803 of the Native American Programs Act of 1974.

Amount of Award: Ten awards for a total of \$193,437.

Project Period: May 2011—September 30, 2011.

SUMMARY: The Administration for Children and Families (ACF), Administration for Native Americans (ANA), announces the award of ten expansion supplement awards to Native American Tribes that are currently combating the epidemic of health issues in Native America. Expansion supplement funds will support activities associated with the First Lady's initiative, *Let's Move! in Indian Country*. Under the program, grantee Tribes have set forth goals and milestones that will benefit Native youth, children, and families.

The following projects will be supported by the expansion supplement awards:

- Native Village of Afognak, Kodiak, AK (\$20,000). The project will include *Let's Move!* activities as part of their summer youth camps.
- Pueblo of Tesuque, Santa Fe, NM (\$20,025). The project will include *Let's Move!* activities in its existing project of building a comprehensive prevention and early intervention program that is focused on building community member awareness of, and ability to, confront challenges.
- Riverside-San Bernardino County Indian Health, Inc., Banning, CA (\$20,000). The project will include healthy living and healthy lifestyles of the *Let's Move!* initiative in its already existing project that focuses on providing pre-marital, dating violence and communication education. The project also provides pre-marital education to pregnant and parenting adolescents.
- Yerington Paiute Tribe, Yerington, NV (\$19,034). This project will include *Let's Move!* activities that support the

development of a family/community wellness support system. The system provides prevention, intervention, referral and follow-up services to community members.

- Cornerstone Ministries, Inc., Crownpoint, NM (\$20,001). This project will implement *Let's Move!* activities in its project to increase the awareness and value of healthy families and will include activities in its training of youth workers to conduct relationship education.

- Eastern Shawnee Tribe of Oklahoma, Wyandotte, OK (\$17,490). This project will include *Let's Move!* activities in its project to encourage healthy eating and exercise to reduce the rate of diabetes among elderly tribal members.

- Leech Lake, Cass Lake, MN (\$19,999). This project will include *Let's Move!* activities in its project to increase relevant academic and cultural content for an intensive in-service for teachers.

- Chickaloon Native Village, Chickaloon, AK (\$16,948). This project will include *Let's Move!* activities in its project that encourages tribal governance and land stewardship of Chickaloon traditional lands by designing and implementing a trails and recreation planning, management, and ecotourism plan.

- White Earth Band of Chippewa, White Earth, MN (\$19,940). This project will include *Let's Move!* activities in its project to improve child well-being and social stability by providing family support services to disadvantaged parents and their children.

- The American Indian Child Resource Center, Oakland, CA (\$20,000). This project will include *Let's Move!* activities in its project to providing life skills training that fosters and promotes decision making, critical thinking, and independent living skills among young Native Americans living in urban environments.

FOR FURTHER INFORMATION CONTACT:

Lillian A. Sparks, Commissioner, Administration for Native Americans, 370 L'Enfant Promenade, SW., Washington, DC 20047. Telephone: 877-922-9262 E-mail: anacommissioner@acf.hhs.gov.

Dated: July 13, 2011.

Kim Romine,

Intergovernmental Affairs Specialist, Administration for Native Americans.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Committee Meeting via Conference Call

AGENCY: President's Committee for People With Intellectual Disabilities (PCPID).

ACTION: Notice.

DATES: Tuesday, August 16, 2011, from 1 p.m. to 2:30 pm E.S.T. This meeting, to be held via audio conference call, is open to the public.

Details for accessing the full Committee Conference Call are cited below:

Toll Free Dial-In Number: 800-779-1436.

Pass Code: PCPID.

Individuals who will need accommodations for a disability in order to participate in the PCPID Meeting via audio conferencing (assistive listening devices, materials in alternative format such as large print or Braille) should notify Genevieve Swift, PCPID Executive Administrative Assistant, at Edith.Swift@acf.hhs.gov, or by telephone at 202-619-0634, no later than Tuesday, August 9, 2011. PCPID will attempt to meet requests for accommodations made after that date, but cannot guarantee ability to grant requests received after this deadline.

Agenda: Committee members will discuss preparation of the PCPID 2011 Report to the President, including its content and format, and related data collection and analysis required to complete the writing of the Report.

Additional Information: For further information, please contact Laverdia Taylor Roach, President's Committee for People with Intellectual Disabilities, The Aerospace Center, Second Floor West, 370 L'Enfant Promenade, SW., Washington, DC 20447.

Telephone: 202-619-0634.

Fax: 202-205-9519.

E-mail: LRoach@acf.hhs.gov.

SUPPLEMENTARY INFORMATION: PCPID acts in an advisory capacity to the

President and the Secretary of Health and Human Services, through the Administration on Developmental Disabilities, on a broad range of topics relating to programs, services and supports for persons with intellectual disabilities. The PCPID Executive Order stipulates that the Committee shall: (1) Provide such advice concerning intellectual disabilities as the President or the Secretary of Health and Human Services may request; and (2) provide

advice to the President concerning the following for people with intellectual disabilities: (A) Expansion of educational opportunities; (B) promotion of homeownership; (C) assurance of workplace integration; (D) improvement of transportation options; (E) expansion of full access to community living; and (F) increasing access to assistive and universally designed technologies.

Dated: July 15, 2011.

Laverdia Taylor Roach,

Director, President's Committee for People with Intellectual Disabilities.

[FR Doc. 2011-18392 Filed 7-20-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0530]

Draft Guidance for Industry and Food and Drug Administration Staff; Mobile Medical Applications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Mobile Medical Applications." FDA is issuing this draft guidance to inform manufacturers, distributors, and other entities about how the FDA intends to apply its regulatory authorities to select software applications intended for use on mobile platforms (mobile applications or "mobile apps"). At this time, FDA intends to apply its regulatory requirements solely to a subset of mobile apps that the Agency is calling mobile medical applications (mobile medical apps). This draft guidance is not final nor is it in effect at this time. **DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 19, 2011

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Mobile Medical Applications" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health (CDRH), Food and Drug Administration,

10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993-0002; or to the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

For devices regulated by CDRH: Bakul Patel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5456, Silver Spring, MD 20993-0002, 301-796-5528.

For devices regulated by CBER: Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852, 301-827-6210.

I. Background

Given the rapid expansion and broad applicability of mobile apps, FDA is issuing this draft guidance to clarify the types of mobile apps to which FDA intends to apply its authority. At this time, FDA intends to apply its regulatory requirements to a subset of mobile apps that the Agency is calling mobile medical apps. For purposes of this guidance, a "mobile medical app" is defined as a mobile app that meets the definition of "device" in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321);¹ and either:

¹ Products that are built with or consist of computer and/or software components or applications are subject to regulation as devices when they meet the definition of a device in section 201(h) of the FD&C Act. That provision defines a device as " * * * an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent * * *," that is " * * * intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man * * *" or " * * * intended to affect the structure or any function of the body of man or other animals * * *."

- Is used as an accessory to a regulated medical device or
- Transforms a mobile platform into a regulated medical device.

This narrowly-tailored approach focuses on a subset of mobile apps that either have traditionally been considered medical devices or affect the performance or functionality of a currently regulated medical device.

Although some mobile apps that do not meet the definition of mobile medical app may meet the FD&C Act's definition of a device, the FDA intends to exercise enforcement discretion² towards those mobile apps.

We welcome comments on all aspects of this guidance as well as the following specific issues:

1. FDA generally considers extensions of medical devices as accessories to those medical devices. Accessories have been typically regulated under the same classification as the connected medical device. However, we recognize potential limitations to this policy for mobile medical apps. FDA seeks comments on how the Agency should approach accessories and particularly mobile medical apps that are accessories to other medical devices so safety and effectiveness can be reasonably assured. For example, one possible approach could be the following:

- An accessory that does not change the intended use of the connected device, but aids in the use of the connected medical device could be regulated as class I. For example, such an accessory would be similar to an infusion pump stand, which is currently classified as a class I device because it supports the intended use of an infusion pump (class II medical device). A mobile medical app that simply supports the intended use of a regulated medical device could be classified as class I with design controls as part of the quality systems requirements.

- An accessory that extends the intended use of the connected medical device could be classified with the connected device. For example, if a mobile medical app that performs more detailed analysis than the connected medical device while maintaining the original intended use, which is data analysis, could be classified in the same classification as the connected medical device.

- An accessory that creates a new intended use from that of the connected

² This means that FDA intends to exercise its discretion to decline to pursue enforcement actions for violations of the FD&C Act and applicable regulations by a manufacturer of a mobile medical app, as specified in this guidance. This does not constitute a change in the requirements of the FD&C Act or any applicable regulations.