FDA Outlines Oversight of Mobile Medical Applications

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SILVER SPRING, Md., July 19, 2011 /PRNewswire-USNewswire/ -- The U.S. Food and Drug Administration today announced it is seeking input on its proposed oversight approach for certain mobile applications specific to medicine or health care called mobile medical applications ("apps") that are designed for use on smartphones and other mobile computing devices. This approach encourages the development of new apps, focuses only on a select group of applications and will not regulate the sale or general consumer use of smartphones or tablets.

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Today, mobile medical applications or "mobile medical apps," include a variety of functions, ranging from monitoring calorie intake, helping people maintain a healthy weight, and allowing doctors to view a patient's radiology images on their mobile communications device. According to Research2Guidance 2010, 500 million smartphone users worldwide will be using a health care application by 2015.

"The use of mobile medical apps on smart phones and tablets is revolutionizing health care delivery," said Jeffrey Shuren, M.D., J.D., director of the FDA's Center for Devices and Radiological Health. "Our draft approach calls for oversight of only those mobile medical apps that present the greatest risk to patients when they don't work as intended."

The agency's draft guidance defines a small subset of mobile medical apps that impact or may impact the performance or functionality of currently regulated medical devices. This subset includes mobile medical apps that:

a. are used as an accessory to medical device already regulated by the FDA (For example, an application that allows a health care professional to make a specific diagnosis by viewing a medical image from a picture archiving and communication system(PACS) on a smartphone or a mobile tablet); or

b. transform a mobile communications device into a regulated medical device b
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