FDA to Host Public Workshop on Mobile Medical Apps Guidance

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The FDA announced that it will host a public workshop on September 12th and 13th, 2011 to gather input on the agency's recently issued draft guidance document, "Mobile Medical Applications." The FDA issued the guidance last month to inform manufacturers, distributors, and other stakeholders about how the FDA intends to apply its medical device regulatory authority to software applications ("apps") that are deployed on mobile devices.

Mobile apps increasingly are being used by individuals as a tool to manage personal health and wellness, as well as to help monitor and manage disease conditions. Mobile apps also are being used by healthcare professionals to assist them in providing medical care to individual patients. Certain apps, for example, allow a user to view radiological images or analyze electrocardiogram data on a mobile device, such as a smart phone or tablet computer, to facilitate a patient diagnosis. While the new FDA draft guidance recognizes that mobile medical apps can provide significant health benefits, mobile apps also may present certain health risks. In addition, the FDA guidance emphasizes that the same mobile medical app may pose additional or different risks depending on the particular mobile device, and features including screen size, contrast ratio, and the environmental conditions in which the device is used (e.g. uncontrolled ambient light).

The new FDA guidance defines a "mobile medical app" as a software application on a mobile platform that is "either (1) used as an accessory to a regulated medical device; or (2) transforms a mobile platform into a regulated medical device." The "mobile medical app" must also meet the definition of "device" under Section 201(h) of the Federal Food, Drug, and Cosmetic Act, which includes an instrument, apparatus, machine, or a related article that is "intended for use in diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease" for humans or other animals."

The planned FDA workshop is intended to provide a forum for public discussion on the FDA's Mobile Medical Application draft guidance document. Specifically, the FDA is seeking the public's perspective on how the agency should regulate mobile medical apps to reasonably ensure their safety and effectiveness, particularly those mobile medical apps that are accessories to other medical devices. The FDA is requesting discussion and comments on the following key issues:

- What factors should FDA consider in determining the risk classification of different types of software that provide clinical decision support ("CDS") functionality?
- How should the FDA assess stand-alone software that provides CDS functionality to reasonably ensure its safety and effectiveness?
- Are there specific controls that manufacturers should implement that could change the risk classification or reduce the premarket data requirements for particular types of stand-alone

software that provide CDS functionality?

Interested stakeholders can either make an oral presentation during the workshop or submit public comments for the record on these issues or any aspect of the draft guidance. The deadline to request an oral presentation during the workshop is September 9, 2011, and public comments must be submitted to the FDA by October 19, 2011. Interested parties can visit the FDA website for specific details on registering for the workshop or submitting public comments.