THE FDA DEFINES ACCESSORIES

The FDA released a draft guidance to clarify what constitutes a medical device accessory and how the agency intends to regulate these devices. "Medical Device Accessories: Defining Accessories and Classification Pathway for New Accessory Types[1]" is available on the FDA website and is open for public comments 90 days from the January 20 publication date – somewhere around Sunday, April 19, so we would conservatively put the last business day for comments at Friday, April 17.

How does this affect Mobile Medical Apps?

For pharmaceutical marketers, the guidance affects only mobile medical apps[2] that interact with a device. The underlying hardware is specifically excluded from the definition of an accessory. It says that a device will not be considered an accessory simply because it runs an app:

> *For example, a mobile phone that is used as a general platform for applications that include mobile medical applications that are medical devices, or an off-the-shelf computer monitor used to display medical data would not be considered accessories unless they are intended for use with such devices.*

This means that your smartphone is not an accessory just because it runs a mobile medical app that has 510(k) certification. However, it leaves the door open for sensors being included in most smartwatches to be classified as medical devices. For example, the Apple Watch, soon to be released, claims to include a heart rate sensor, and both LG Electronics and Samsung have 510(k) clearances for devices[3]:

- Samsung: "cardiology signal transmitter"
- LG Electronics: "LG Smarthealth"

The FDA was careful to close that door for general health apps in the other recent draft guidance: "General Wellness: Policy for Low Risk Devices.[4]" The combination of these two guidances should allow for general fitness and weight loss use of the built in sensors without incurring the FDA's wrath.

1 http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM429672.pdf
2 http://www.klick.com/health/news/blog/mhealth/fda-releases-final-guidance-on-mobile-medical-apps/
3 http://www.klick.com/health/news/blog/mhealth/top-fda-510k-clearances-for-2014/
4 http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm429674.pdf

Types of Accessories

According to the definitions in the draft guidance there are three types of accessories:

- *Support*: provides assistance to the primary operation of the parent device
- *Supplement*: adds new functionality to the operation of the parent device
- *Augment*: allows the operation of the parent device more safely or effectively

The classification of a device follows two steps and a request from the FDA to follow its "*de Novo*" process to request its input. The steps are essentially:

- Is the device an accessory in that it supports a parent device in one of the three defined ways?
- What are the risks involved in using the accessory with the parent device?
- If there is doubt as to the classification of the accessory, the FDA recommends using its "*de Novo*" process to get an opinion

What Does This Mean for Healthcare Marketers?

For healthcare marketers considering apps this means two things:

- If you are creating an app that is intended to work with an existing medical device, say a piece of hardware like an insulin pump or even a mobile medical app, you need to review the app to see if it falls into the FDA's definition of an accessory. If it does, you will need to get it approved but it may not be as onerous as you might fear.

- If any of the platforms available are deemed medical devices you will need to review this guidance to see if your app is considered an accessory. This will most likely not be an issue, but LG recently acquired a 510(k) certification for a cardiovascular sensor and so did Samsung for its S Health app[3] so any apps that use those sensors will need to be reviewed against this guidance to see if they are considered accessories.

This draft guidance really is just a long definition of the term "accessory" and to the untrained eye it seems pretty straightforward. Readers are encouraged to talk with their regulatory groups about what this means for their mobile app plans.

Questions?

If you have any questions about these developments, reach out to your account representative or contact:

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