Medical Device Alert

January 20, 2015

FDA Proposes Additional Flexibility for Mobile Health Products

Draft Guidances Address General Wellness Products and Device Accessories

The U.S. Food and Drug Administration (FDA or "the Agency") has announced two more key parameters of its regulatory approach to mobile health products, at a time when Congress continues to show interest in clarifying the scope of FDA's regulatory authority over mobile health products and other medical software. On January 16, 2015, the Agency released two Draft Guidance documents that outline its proposed approach to low-risk devices intended to promote general wellness ("Wellness Guidance") and to medical device accessories ("Accessories Guidance").

- Broadly speaking, FDA proposes not to regulate products intended only for general wellness. If finalized, this policy would reduce uncertainty for the makers of mobile applications ("apps") and other technology designed to promote general wellness, and eliminate the need for FDA preapproval in many circumstances.

- FDA has also proposed to classify medical device accessories based on the risks related to the accessories themselves when used as intended, and not based on the risk of the device with which they are to be used. This would represent a significant shift in the Agency's stated approach. It remains to be seen whether FDA's recommended method to obtain classifications—the *de novo* process—will prove effective for sponsors of device accessories.

The Draft Guidances were published in the *Federal Register* on January 20th, and comments are due by April 20, 2015.

Wellness Guidance

The Wellness Guidance proposed criteria for wellness devices and apps that FDA will actively regulate as medical devices and those for which the Agency will exercise enforcement discretion. FDA proposes not to enforce regulatory requirements for products intended only for general wellness that the Agency views as "low risk." Specifically, FDA's Center for Devices and Radiological Health (CDRH) "does not intend to examine low-risk general wellness products to determine whether they are devices within the meaning of the [Food, Drug, and Cosmetic Act (FDCA)] or, if they are devices, whether they comply with the premarket review and post-market regulatory requirements for devices under the [FDCA] and implementing regulations, including, but not limited to:" (i) registration and listing, and premarket notification requirements, (ii) labeling requirements, (iii) good manufacturing requirements as set forth in the Quality Systems Regulation and (iv) Medical Device Reporting (MDR) requirements.

The guidance applies to a general wellness product that is "low-risk" and that has:

1. an intended use that relates to maintaining or encouraging a general state of health or healthy activity; or

2. an intended use claim that associates the role of a healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions, and where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition.

The Wellness Guidance provides a flowchart to assist product developers in applying the proposed regulatory approach.

In general, the draft guidance is consistent with previous FDA guidance on mobile medical apps and the Health IT Framework developed by FDA in conjunction with the Office of the National Coordinator for Health Information Technology (ONC) and the Federal Communications Commission (FCC) pursuant to the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA). The proposed inclusion of certain disease-related claims is noteworthy, and provides clarity for developers that seek to link general health claims to reductions in the risk or effect of chronic diseases or medical conditions. Notably, however, FDA has cautioned that such references should only be made if the association "is well understood." If FDA believes the claim is not generally recognized and supported, the Agency would potentially subject the product to the full device regulatory requirements.

Accessories Guidance

The Accessories Guidance aims to tackle a longstanding topic of confusion and controversy. Historically, FDA has taken the position that an accessory is to be classified along with the highest-risk device with which it is intended for use. In many cases, however, an accessory itself is low risk, and arguably did not warrant the heightened regulatory oversight applicable to high-risk devices. In the draft guidance, FDA has proposed a different approach, under which a device accessory would be regulated based on the risks that the accessory itself presents when used as intended with its "parent" devices—regardless of the risk level of that parent device:

> Classifying an accessory in the same class as its parent device is appropriate when the accessory, when used as intended, meets the criteria for placement in that class. However, some accessories can have a lower risk profile than that of their parent device and, therefore, may warrant being regulated in a lower class. For example, an accessory to a Class III parent device may pose lower risk that could be mitigated through general controls or general and special controls, and thus could be regulated as Class I or Class II.[1]

FDA also seeks to clarify what constitutes an accessory, as opposed to a stand-alone device or a component of a device or system. Under the draft guidance, "accessories" are items intended for use with one or more parent devices and items "intended to support, supplement, and/or augment the

[1] Draft Guidance for Industry and Food and Drug Administration Staff, "Medical Device Accessories: Defining Accessories and Classification Pathway for New Accessory Types" (January 2015), available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM429672.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery

performance of one or more parent devices." The proposed approach is potentially significant in lowering the barriers to more complex device systems, facilitating connectivity and interoperability, and using mobile platforms for health care functionalities.

The Accessories Guidance also recommends an approach for accessories to obtain separate, risk-based classifications, suggesting that their sponsors avail themselves of the *de novo* process and providing instructions for doing so. It is not unprecedented for FDA separately to classify devices that often serve as accessories to other devices. For example, in 2011 the Agency down-classified Medical Device Data Systems (MDDS), which are often used as accessories to other higher-risk devices, from Class III to Class I.[2] The *de novo* process can be time consuming and resource intensive, and it remains to be seen how frequently sponsors would have sufficient incentives to seek proactive reclassifications of accessories.

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Congress has an ambitious legislative agenda relating to FDA-regulated industries, epitomized by the House Energy and Commerce Committee's 21st Century Cures initiative. Several legislative proposals under consideration in Congress would either clarify or lower regulatory requirements relating to accessories and to the types of mobile health apps often intended for general wellness. Members of Congress likely will track reactions and comments to these Draft Guidances carefully as they consider how these announcements impact their legislative priorities for 2015.

[2] 76 Fed. Reg. 8637 (Feb. 15, 2011). FDA subsequently proposed to exercise enforcement discretion for MDDS. See Draft Guidance for Industry and Food and Drug Administration Staff, "Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices" (June 2014), *available at* http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm401785.htm.

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