Published on *The National Law Review* https://natlawreview.com

FDA Proposes to Apply Risk-Based Framework to Accessory Devices

Article By:

Ellen L. Janos

In another effort to bring some clarity to its regulation of devices, the FDA has released draft guidance on how its risk-based framework applies to accessory devices (the “Draft Guidance”). This development is welcome news for the *mHealth community*.

What is an accessory? The Draft Guidance considers an accessory to be an article that is intended for use with one or more parent devices and is intended to support, supplement, and/or augment the performance of one or more parent devices. While accessories were typically included in the same class as the parent device, the FDA now recognizes that some accessories can have a lower risk profile than that of their parent device and may warrant being regulated in a lower class. For these lower risk products, the Draft Guidance encourages the use of the FDA de novo classification process to request risk-based classification of accessories of a new type.

The FDA is seeking comments on the Draft Guidance by April 15, 2015.

National Law Review, Volume V, Number 16