THE
NATIONAL LAW REVIEW

FDA Issues Final Drug and Device Classification Guidance

Friday, September 29, 2017

Summary

This week, the FDA published final guidance outlining the agency's current thinking with respect to the classification of products as drugs or devices, respectively. The final guidance summarizes the agency's position with respect to several elements of the statutory definition of "device," such as when a product that exhibits chemical action may nevertheless be considered a device. Importantly, the final guidance does not include two controversial provisions from earlier draft guidance.

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On the Subject

Health Law & Managed Care
Biotech, Food, Drug
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In Depth

On September 25, 2017, the US Food and Drug Administration (FDA) published final guidance—entitled *Classification of Products as Drugs and Devices & Additional Product Classification Issues* (hereinafter, the Final Guidance)—outlining the agency's current thinking with respect to the classification of products as drugs and devices, respectively.

Products that meet the Federal Food, Drug and Cosmetic Act's (the Act's) definition of a "device" also meet the Act's definition of a "drug" because of the broad definition of the latter term. For a product to meet the more restrictive "device" definition, however, the product must be an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other "similar or related article"; not achieve its "primary intended purposes" through "chemical action within or on the body" of man or other animals; and not be dependent upon being metabolized for the achievement of its primary intended purposes. In the Final Guidance, the agency outlines its current thinking with respect to several elements of the statutory definition of "device":

- **"Similar or related article."** The question of whether a product is a "similar or related article" may arise when products are in liquid, semi-liquid, gel, gas or powder form. In the Final Guidance, the FDA clarifies that products in such forms are appropriately considered "similar or related articles."
- **"Primary intended purposes."** The Final Guidance mirrors the language of the Act, and states that a product that has chemical action "could be a device if it does not achieve its primary intended purposes through [such] chemical action."
- **"Chemical action."** A product exhibits "chemical action" if it "interacts at the molecular level with bodily components (*e.g.*, cells or tissues) to mediate (including promoting or inhibiting) a bodily response, or with foreign entities (*e.g.*, organisms or chemicals) so as to alter that entity's interaction with the body."
    - An interaction at the "molecular level" occurs through either chemical reaction (*i.e.,* formation or breaking of covalent or ionic bonds), intermolecular forces (*e.g.*, electrostatic interactions), or both.
    - The mere exchange of non-chemical energy (*e.g.*, electromagnetic or thermal energy) between a product and the body would not constitute chemical action.
    - **"Within or on the body."** While determining whether chemical action occurs within or on the body is generally straightforward, the agency has occasionally considered certain situations where the

result may be less clear (*e.g.*, the agency previously determined that chemical action occurring in a kidney hemodialysis machine is not occurring "within or on the body").

The Final Guidance provides examples of products that do (or do not) achieve their primary intended purposes through chemical action within or on the body.

The Final Guidance also includes several provisions related to the process for classifying products as drugs and devices. Key takeaways from this section of the Final Guidance include:

- **If the classification of a product as a drug, device, biological product or combination product is unclear or in dispute, product sponsors may submit a Request for Designation (RFD) to the FDA's Office of Combination Products (OCP).** In the RFD, sponsors should recommend a classification and explain the basis for that recommendation. In general, OCP will respond to sponsors in writing within 60 days of RFD filing, identifying the classification of the product as a drug, device, biological product or combination product. If the agency does not respond in writing within 60 days, the sponsor's recommendation for the product's classification is considered the final determination.
- **When deciding whether a product should be classified as a drug or device, the agency relies on the scientific data available to the agency at the time of the determination concerning the product for its proposed use(s)/indication(s).** For this reason, a sponsor seeking a classification determination should present all available data and other information potentially relevant to this determination (including evidence that does not support its recommendation). The focus of FDA's classification analysis is on how the product would be expected to achieve its primary intended purposes, assuming it is capable of achieving its primary intended purposes at all.
    - Two products with exactly the same composition can be classified differently based on their primary intended purposes.
    - **The FDA may modify a determination regarding the classification of a product (or the Center of the FDA that will regulate the product) either with the written consent of the sponsor or for public health reasons based on scientific evidence.** A new determination may be appropriate if there is a change in indication, or if the sponsor or FDA becomes aware of additional information that reveals the means by which the product achieves its primary intended purposes differ from what was originally described in the RFD.

Implications

The FDA consolidates and finalizes two guidance documents first proposed in June 2011 in the Final Guidance. In one of the draft guidance documents, the FDA controversially took the position that (1) for a product with multiple therapeutic effects, each effect would be considered a "primary intended purpose" for the purposes of product classification, regardless of the extent to which such effects are responsible for the overall therapeutic action of the product and (2) a product that depends *even in part* on chemical action within or on the body for *any* of its therapeutic effects would not be considered a device. If implemented, these policies would have resulted in more products being required to go through the more burdensome drug approval process. **However, neither of these provisions is included in the Final Guidance document.** Given the substantial criticism (and legal challenges) the agency faced in the wake of the proposal of such policies, the omission of such language was likely intentional. Nevertheless, it is unclear whether the agency intends (or will be permitted) to apply such standards in the future if it chooses to do so. As such, interested entities should continue to monitor communications from the agency to assess whether this omission truly heralds a substantive shift in the agency's policy.