FDA Issues Guidance on Drug and Device Classifications

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On September 26, 2017, the Food and Drug Administration (FDA) announced the availability of a final guidance entitled Classification of Products as Drugs and Devices & Additional Product Classification Issues to clarify FDA's thinking on classifying products as drugs, devices, biological products, or combination products. In the guidance, FDA sets forth some general concepts about its approach to the classification question and also provides illustrative examples of classification determinations with some limited explanation. The guidance also describes the process for requesting a formal classification determination (RFD) from FDA. This guidance finalizes and combines two draft guidance documents on the subject – *"Classification of Products as Drugs and Devices & Additional Product Classification Issues" and "Interpretation of the Term 'Chemical Action' in the Definition of Device under Section 201(h) of the Federal Food, Drug, and Cosmetic Act."*

Classification of a Product as a Drug or Device

It is not always obvious or indisputable whether a particular medical product is appropriately classified as a drug or device based solely on the statutory definitions of "drug" and "device" found in the Food, Drug, & Cosmetic Act ("FD&C Act"), or whether FDA will agree with your conclusion. FDA will consider both the specific definitions in the statute[1] and the scientific data available to FDA (including the data submitted by the sponsor) in making the classification determination.

All medical products meet the broader definition of a "drug" The classification determination thus depends on whether a product also meets the more restrictive language in the "device" definition, which requires that the product be:

- an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, and
- not achieve its primary intended purpose through chemical action within or on the body of man or other animals and which is not dependent on being metabolized for the achievement of its primary intended purpose.

In the final guidance, FDA elaborates generally on how it interprets key portions of this definition

1 Section 201(g) of the FD&C Act defines "drugs" to mean:

> (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any articles specified in clause (A), (B), or (C) ….

Section 201(h) of the FD&C Act defines a "device" to mean:

> [A]n instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part or accessory, which is—
> (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them; (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and
>
> which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

and describes common issues that arise in interpreting the more restrictive "device" definition.

What is a "similar or related article"?

According to FDA, issues commonly arise as to whether a product may be considered a "similar or related article" under the definition of a "device." Specifically, FDA clarifies that in order for a product to be a device it doesn't have to fit the first part of the definition, *i.e.*, it doesn't need to be considered an instrument or machine or contrivance or any of the other listed types of devices. For example, a product in a liquid, semi-liquid, gel, gas, or powder form could be classified as a "similar or related article" and thus considered a device, as long as it satisfies the remainder of the definition. FDA gives the examples of the following which could be considered devices: "gels or powders that are put on the skin as a barrier, gases used as space fillers, or liquids used to clean either surgical instruments or contact lenses."

How is the "primary intended purpose" determined?

Questions also arise about what it means for an article to not achieve its "primary intended purposes through chemical action within or on the body of man or other animals." A product's having some chemical action does not preclude it from being classified as a device, if the device does not achieve its primary intended purpose through that chemical action. FDA cites the example of a hip joint replacement implant that has a *primary intended purpose* of restoring movement. Even though the implant may also elicit a chemical action in the form of a foreign body response, the implant could be classified as a device, because the chemical action does not achieve the product's primary intended purpose.
First, the ad included efficacy claims, but failed to include important risk information.

What is "chemical action"?

The guidance also clarifies FDA's interpretation of the term "chemical action," providing that the "term must be read in the context of the statutory definition of 'device' as a whole." The final guidance provides that 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.

FDA elaborates that an interaction at the molecular level occurs through a chemical reaction (i.e., the formation or break down of covalent or ionic bonds), or through an intermolecular force, such as an electrostatic interaction, or both. FDA advises that "[t]he mere exchange of non-chemical energy (e.g., electromagnetic or thermal energy) between a product and the body would not constitute 'chemical action.'"

What constitutes "within or on the body?"

FDA advises that the determination of whether a chemical action occurs "within or on the body" is "generally a straightforward matter." If the chemical action occurs inside the body or on the surface of the body, it is considered to be "within or on the body" for purposes of the definition. As an example, FDA cited the chemical action of an antimicrobial agent that is used to clean a surgical instrument prior to the instrument being used, as not occurring within or on the body.

FDA also cited less clear examples, noting that a chemical action which occurs only within an extracorporeal device (as an example, a kidney hemodialysis machine) is not considered to be occurring "within or on the body." Similarly, the chemical action of a transport solution to preserve a donor organ for transplantation while in an organ transport container is not considered to be occurring "within or on the body."

Illustrative Examples

The guidance includes a number of examples in Table 1 and Table 2 to illustrate the application of the device definition and which products achieve their "primary intended purposes through chemical action within or on the body." Some of these are fairly obvious (if one can ever say such a thing), but several provide useful insight into potentially more controversial product classifications.

Request for Determination

The final guidance also includes an overview of the RFD process. Of particular note, FDA advised that when a company submits an RFD to the Office of Combination Products (OCP), the sponsor should include a recommendation for the product classification and support for the recommendation. The support for the recommendation should include data which justify the sponsor's recommendation, as well as any data or other relevant information counter to the recommendation.

In addition, the guidance notes that, under certain circumstances, the OCP may modify its determination regarding the classification of a product. A new determination may be appropriate, for instance, if there is a change in a proposed indication for use, or if the sponsor or FDA becomes aware of additional information that shows that the means in which the product achieves its primary intended purposes differ from what was originally reported in the RFD.

AGG Observations

- Although the types of products that could require classification and how they work are essentially infinite now, let alone in the years to come, the guidance and particularly the examples are useful.
- Sponsors requesting a determination should review these examples and the balance of the guidance carefully to see if they may need to submit an RFD. If an RFD is in order, it is critical to use the terminology and examples in the guidance to demonstrate how your product is either similar or can be distinguished.
- Although FDA provided a number of examples and further guidance on classification issues, the agency still has considerable discretion to make classification determinations.

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