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CLIENT ALERT

FDA Issues Draft Guidance to Clarify Referencing of the Terms "Device" and "Counterfeit Device"

DECEMBER 22, 2021

Earlier this month, in an effort to promote the consistent use of terms and definitions in the Federal Food, Drug, and Cosmetic Act ("FD&C Act"), the Food and Drug Administration ("FDA" or the "Agency") issued draft guidance (the "Guidance") to clarify references to the terms "device" and "counterfeit device."

The Guidance comes after recent amendments to section 201(h) of the FD&C Act and as a result of the enactment of the Safeguarding Therapeutics Act ("STA").[1]

See FDA's Draft Guidance Referencing the Definition of "Device" in the Federal FD&C Act in Guidance, Regulatory Documents, Communications, and Other Public Documents, *available at* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/referencing-definition-device-federal-food-drug-and-cosmetic-act-guidance-regulatory-documents?utm_medium=email&utm_source=govdelivery.

BACKGROUND

The definition of "device" was codified at section 201(h) of the FD&C Act. However, upon the enactment of the STA, the definition of "device" shifted to section 201(h)(1) and a new definition of "counterfeit device" was added at section 201(h)(2). The STA, however, did not make any changes to the existing substance of the "device" definition. The purpose of this recent Guidance is to clarify how FDA will interpret existing references to section 201(h) of the FD&C Act and how it intends to reference the definitions of "device" and "counterfeit device" going forward in guidance, regulatory documents, and other communications and documents from FDA staff, industry, and other stakeholders.

In its entirety, section 201(h) of the FD&C Act now reads:

> (h)(1) the term "device" (except when used in paragraph (n) of this section and in sections 301(i), 403(f), 502(c), and 602(c)) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—
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> > (A) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(B) 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

(C) 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. The term "device" does not include software functions excluded pursuant to section 520(o).

(2) The term "counterfeit device" means a device which, or the container, packaging, or labeling of which, without authorization, bears a trademark, trade name, or other identifying mark or imprint, or any likeness thereof, or is manufactured using a design, of a device manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such device and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other device manufacturer, processor, packer, or distributor.

Existing References to Section 201(h) of the FD&C Act and the Term "Device"

FDA provides that, "[i]n statutes, regulations, guidance, other statements of policy, judicial filings, warning letters, untitled letters, and many other public documents, there are specific references to the term "device" as that term is defined in section 201(h) of the FD&C Act."

In these documents, when the purpose of the reference to section 201(h) is to define the term "device," FDA considers there to be "no ambiguity" in interpreting the reference to refer to the "device" definition that remains within subsection (h).

Any **existing** references to section (201)(h) in FDA policy documents, including polices that describe FDA intention to enforce certain requirements under the FD&C Act, are **not** to be interpreted to apply to counterfeit devices because, although counterfeit devices may themselves meet the definition of "device," FDA did not intend to exercise enforcement discretion or extend certain policies to counterfeit devices.

Future References to the Term "Device"

Following the enactment of the STA, FDA aims to follow certain conventions when referencing the terms "device" and "counterfeit device." In the interest of consistency with prior documents, FDA will generally continue to reference section 201(h) of the FD&C Act for the definition of device.

FDA may utilize more precise references to section 201(h)(1) of the FD&C Act when quoting the definition of "device," referring to statements contained in subparagraphs (A) through (C) of section 201(h)(1) of the FD&C Act, or maintaining consistency with other definitions in the same document.

In the event FDA intends to reference the definition of a "counterfeit device" in a document, FDA aims to do so expressly with a reference to section 201(h)(2) of the FD&C Act.

References to the Term "Device" in Documents FDA Receives

FDA indicates that the Agency will attempt to employ the same conventions described above when interpreting documents received from industry and other stakeholders. To the extent industry and other stakeholders must make references to the term "device" in premarket submissions, reports, and other communications and inquiries to FDA, FDA encourages them to conform references to the recommendations described in the Guidance.

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[1] Pub. L. 116-304, 134 Stat. 4915.
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