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Referencing the Definition of "Device" in the Federal Food, Drug, and Cosmetic Act in Guidance, Regulatory Documents, Communications, and Other Public Documents

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Guidance for Industry and Food and Drug Administration Staff

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For questions about this document regarding CDRH-regulated devices, contact the CDRH Guidance Program in the Office of Policy at CDRH-Guidance@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov.

U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

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Preface

Public Comment

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Referencing the Definition of "Device" in the Federal Food, Drug, and Cosmetic Act in Guidance, Regulatory Documents, Communications, and Other Public Documents

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Guidance for Industry and Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

The U.S. Food and Drug Administration (FDA or the Agency) recommends the consistent use of terms and definitions of legal significance. In light of recent amendments to section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) as a result of the enactment of the Safeguarding Therapeutics Act,[1] FDA is issuing this guidance to promote clarity regarding references to the terms "device" and "counterfeit device."

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Background

For many years, the definition of "device" has been codified at section 201(h) of the FD&C Act. Upon enactment of the Safeguarding Therapeutics Act, the definition of "device" was

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

redesignated as paragraph (1) of subsection (h) and a new definition of "counterfeit device" was codified at paragraph (2) of subsection (h). 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.

III. Scope

The Safeguarding Therapeutics Act adds and defines a new term: "counterfeit device" (section 201(h)(2) of the FD&C Act).[2] It also redesignates the definition of "device" (section 201(h)(1) of the FD&C Act).[3] It does not make any changes to the existing "device" definition.

In addition, under the Safeguarding Therapeutics Act, articles that appear to be counterfeit devices are subject to refusal of admission into the United States.[4] The Safeguarding Therapeutics Act also grants FDA new authority to destroy certain devices refused admission.[5] These additional amendments to the FD&C Act are being implemented through separate policy documents and are beyond the scope of this guidance.

FDA is issuing this guidance to clarify how the Agency interprets existing references to section 201(h) of the FD&C Act and how we intend to reference the definitions of "device" and

[2] Pub. L. 116-304, section 2(b), 134 Stat. 4916, amending section 201(h) of the FD&C Act.
[3] *Id*.
[4] Pub. L. 116-304, section 2(a), 134 Stat. 4915, amending section 801(a) of the FD&C Act.
[5] *Id*.

"counterfeit device" going forward. This guidance is intended to provide clarity on references to the terms "device" and "counterfeit device" – as well as references to section 201(h) of the FD&C Act – in guidance, regulatory documents, and other communications and documents for FDA staff, industry, and other stakeholders.

IV. Policy

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

In 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. For example, the Public Readiness and Emergency Preparedness (PREP) Act defines a "covered countermeasure" to include a "device (as such term is defined by section 201(h) of the Federal Food, Drug and Cosmetic Act) . . .".[6] In these instances, FDA understands that the intent – whether Congressional, Agency, or otherwise – was to refer to the definition of "device" that was codified at section 201(h) of the FD&C Act at the time the reference was made (as discussed above, the definition of "device" is now codified at section 201(h)(1) as a result of the enactment of the Safeguarding Therapeutics Act).

When the purpose of the reference to section 201(h) of the FD&C Act is to define or refer to the term "device," there should be no ambiguity about which term is being referenced. The "device" definition remains *within* subsection (h).

Any existing references made to section 201(h) of the FD&C Act in FDA policy documents, including enforcement policies that describe FDA's intent not to enforce certain requirements under the FD&C Act, are not intended to apply to counterfeit devices. For example, in our guidance "Policy for Device Software Functions and Mobile Medical Applications,"[7] we announced an enforcement policy that describes the circumstances in which FDA generally intends to exercise enforcement discretion (meaning FDA does not intend to enforce certain requirements of the FD&C Act) for certain software functions that meet the definition of "device" as defined in section 201(h) of the FD&C Act. Although counterfeit devices may themselves meet the definition of "device," it was not FDA's intent to exercise enforcement discretion or otherwise extend certain policies to counterfeit devices.[8]

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[6] 42 U.S.C. 247d–6d(i)(1)(C).

[7] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-device-software-functions-and-mobile-medical-applications.

[8] Products that meet the definition of a "counterfeit device" under section 201(h)(2) of the FD&C Act would generally be in violation of the FD&C Act, e.g., would be deemed misbranded under section 502 of the FD&C Act. Further, as discussed above, the Safeguarding Therapeutics Act amended section 801(a) of the FD&C Act to make clear that counterfeit devices (as defined in section 201(h)(2)) are subject to refusal of admission into the United States. Additionally, counterfeit devices may be harmful to health. Consequently, FDA's enforcement policies applicable to devices that describe FDA's intent not to enforce certain requirements of the FD&C Act do not apply to counterfeit devices.

B. Future References to the Term "Device"

Following enactment of the Safeguarding Therapeutics Act, FDA aims to follow certain conventions when referencing the terms "device" and "counterfeit device." For consistency with prior documents, we will generally continue to reference section 201(h) of the FD&C Act for the definition of "device." For example, a future FDA guidance might read:

> Section 3060(a) of the 21st Century Cures Act amended the FD&C Act to add section 520(o), which excludes certain software functions from the definition of device in section 201(h) of the FD&C Act.

In certain instances, FDA and others may utilize the more precise reference to section 201(h)(1) of the FD&C Act. Instances in which FDA may opt to reference paragraph (1) of subsection (h) specifically include quoting the definition of "device" in part or in its entirety, referring to statements contained in subparagraphs (A) through (C), or maintaining consistency with other definitions in the same document.[9]

For example, when referring to the structure/function prong of the "device" definition, FDA may cite to subparagraph (C) of section 201(h)(1) of the FD&C Act for precision:

> FDA considers needle penetration beyond the stratum corneum as a result of the design or technology of a microneedling product as evidence that it may be "intended to affect the structure or any function of the body" under section 201(h)(1)(C) of FD&C Act.

As another example, the preamble to a proposed rule could refer to the definitions of a "drug" and a "device" at sections 201(g)(1) and 201(h)(1) of the FD&C Act, respectively, for consistency:

> Among the provisions that provide authority for this proposed rule are sections 201 and 503(g) of the FD&C Act, and section 351(i) of the Public Health Service Act (PHS Act). Section 201 of the FD&C Act defines "drug" (subsection (g)(1)) and "device" (subsection (h)(1)); and section 503(g) of the FD&C Act provides that combination products are those "that constitute a combination of a drug, device, or biological product." Section 351(i) of the PHS Act defines "biological product" (42 U.S.C. 262(i)), and section 351(j) of the PHS Act provides that the requirements of the FD&C Act apply to biological products (42 U.S.C. 262(j)).

Most importantly, whether FDA cites to section 201(h) or to 201(h)(1) of the FD&C Act, FDA's intent should not be understood to be any different. In either case, we are intending to refer readers to the definition of "device" contained in paragraph (1) of section 201(h) of the FD&C Act, or to otherwise apply policies to or reference devices that meet the definition in paragraph (1), but not to counterfeit devices defined in paragraph (2). Deviations from the conventions described in this guidance document should not alone be considered to have legal significance.

[9] The definition of drug is codified at section 201(g)(1) of the FD&C Act, though FDA, Congress, and others alternate between referencing subsection (g) and (g)(1).

In the event that 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.

C. References to the Term "Device" in Documents FDA Receives

FDA expects to receive documents, such as premarket submissions, reports, and other communications and inquiries, from industry and other stakeholders that include references to the term "device" and to the corresponding provisions of the FD&C Act. As appropriate, FDA will attempt to employ the same conventions described in this guidance document when interpreting documents that we receive from such stakeholders. Thus, we encourage stakeholders to align with the recommendations described herein to the extent practicable.