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Client Alert

FDA & Life Sciences Practice Group

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FDA Issues Draft Guidance on Custom Devices

Exemption for Custom Devices Remains Narrow

On January 14, 2014, the U.S. Food and Drug Administration (FDA or "the Agency") released a draft guidance document titled *Custom Device Exemption*.[1] The draft guidance describes how the Agency interprets the custom device provision in section 520(b) of the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 360j(b), as modified in 2012 by the Food and Drug Administration Safety and Innovation Act (FDASIA). Specifically, the draft guidance explains how FDA will apply the statutory criteria for a custom device, including the "five [custom] units per year of a particular device type" requirement and describes the information that FDA expects manufacturers' required annual reports to contain, if the Agency finalizes the draft guidance. The draft guidance suggests that FDA will continue to narrowly construe the custom device exemption and that the Agency expects manufacturers to carefully consider whether a device type meets the criteria and document such determinations. Comments on the draft guidance must be submitted by March 17, 2014, and should reference docket number FDA-2013-D-1601.

Custom Device Exemption and Definitions

FDASIA revised the FDCA's custom device exemption that allows manufacturers to provide custom devices without obtaining premarket approval or clearance. Section 505(b)(1) of the FDCA defines a custom device as a device that:

(A) is created or modified based on an order from a physician or dentist;

(B) "necessarily deviates" from a performance standard or PMA requirement;

(C) is "not generally available" in the United States in finished form;

(D) is designed to treat a unique pathology or physiological condition that no other domestically available device can treat;

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(E) (i) is intended to meet the special needs of the physician or dentist ("physician-centric"), or (ii) is intended for use by an individual patient named in the physician or dentist's order ("patient-centric");

(F) is assembled from components or manufactured on a case-by-case basis; and

(G) may have common, standardized design characteristics, chemical and material compositions, and manufacturing processes as commercial devices.

Section 505(b)(2) places additional limitations on the custom device exception. Under that section, a device can only qualify as a custom device if it is intended to treat "a sufficiently rare condition" for which conducting clinical investigations would be "impractical." In addition, the section limits the production of custom devices to "no more than 5 units per year of a particular device type." Further, manufacturers should provide annual reports to FDA regarding the production of custom devices.

FDA's definitions of *necessarily deviates* and *sufficiently rare condition* both relate back to the requirement that conducting clinical investigations of the custom device would be impractical given the rare incidence or prevalence of the condition requiring the custom device.[2] The definitions of *unique pathology* and *unique physiological condition*, on the other hand, are tied to the requirement that there be no other device that is domestically available and is able to treat the pathology or condition.[3] The terms *not generally available* and *special need* seem to serve both purposes.

Five Units of a Particular Device Type

The draft guidance also defines *device type*, in the context of the requirement that manufacturers provide no more than five custom device units of a particular device type per year. The draft guidance incorporates the definition of *generic type of device* contained in 21 C.F.R. § 860.3(i): "a grouping of devices that do not differ significantly in purpose, design, materials, energy source, function, or any other feature related to safety and effectiveness, and for which similar regulatory controls are sufficient to provide reasonable assurance of safety and effectiveness."[4] The draft guidance further elaborates that in the custom device context, *device type* "describes devices with common design characteristics and indication/intended use, such as those devices defined by an FDA classification regulation or product code."[5]

FDA's interpretation that all devices with the same product code constitute one type of device could severely limit a manufacturer's ability to provide custom devices. For example, if a company manufactures three different models of semi-constrained and cemented metal or polymer hip prostheses under the product code JDI, it could provide a total of five custom devices across all three models in any one year. The firm would not be permitted to produce five custom versions of each model (for a total of fifteen custom devices).

The reference to an FDA classification regulation in connection with the five unit limit has the potential to even more severely limit the ability to provide custom devices. Some classification regulations are very broad and cover a large number of product codes and/or multiple devices under one product code. For example, the classification regulation for Surgical Mesh, 21 C.F.R. § 878.3300, covers forty-one product codes for a wide variety of uses – chest wall, abdominal wall, plastic and reconstructive surgery, orthopedic, stress urinary incontinence, and organ support. Furthermore, the product codes within the classification regulation cover absorbable and non-absorbable meshes, as well as collagen-based mesh products. Under FDA's definition, all of these devices could be the same device type and subject to the same five-device limit each year.

The draft guidance does provide some flexibility in situations that require the manufacturer to produce extra units for a physician.[6] Specifically, if the company produces extra units for a patient-centric procedure because it is not known which size the patient will require, only the unit that is implanted in or provided to the patient counts toward the five unit per device type limit, provided that the physician returns the unused units to the manufacturer and the

manufacturer does not redistribute the returned units. This will require firms to carefully track the provision and return of extra units of varying sizes. Accordingly, companies should consider mechanisms or procedures to ensure that any extra units are returned (*e.g.*, written agreements or standardized follow-up with physicians). Once the extra units are returned, FDA recommends that they be destroyed and that a signed record of the destruction be added to the device history record.

FDA also permits an exception to the strict five unit per device type rule in circumstances in which a patient requires multiple custom devices of the same type, such as in bilateral conditions or treatments.[7] In these cases, FDA will count multiple devices as one unit for the purpose of the annual limit, provided that all are provided to or implanted in the patient within the same reporting year.

The draft guidance also excludes revisions and servicing of existing, valid custom devices from the five units of a particular device type limit, as long as the revision or service "is performed in furtherance of meeting the special needs of the person, physician, or dentist for whom the custom device was initially intended prior to such revision and/or servicing."[8] Although such revisions and servicing are excluded from the annual five unit limit, they should nevertheless be included in the annual report.[9]

The draft guidance document states that if a device does not meet all of the requirements for a custom device, the Company may request FDA approval for compassionate use of the device. If this option might be applicable, manufacturers should be aware of and adhere to FDA's separate requirements and policies for compassionate use of medical devices.

Annual Reports

Section VI of the draft guidance provides FDA's expectations for the content of manufacturers' annual reports regarding custom devices and contains templates for elements of the report in Appendices I and II. FDA explains that "[t]he annual report should summarize the number of custom devices manufactured and distributed in the United States during a . . . given calendar year."[10] The first report filed by a manufacturer, however, should contain information about custom devices dating back to the effective date of FDASIA (July 9, 2012). FDA will not enforce the reporting requirement until the end of the calendar year following publication of the final guidance, but the Agency nevertheless encourages firms to begin submitting reports in advance of that time.[11] If firms do not submit annual reports prior to the finalization of the guidance, they should nevertheless keep careful records of custom devices because any custom devices provided between July 9, 2012 and the finalization of the guidance document should be included in the first report. Annual reports will be due by March 31 of the year following each reporting period.

Annual reports should contain a cover letter, a signed certification statement, and detailed information on both patient-centric and physician-centric custom devices. The level of detail that FDA proposes to require for each custom device provided in a calendar year demonstrates that the Agency expects manufacturers to evaluate whether the ordered device meets the custom device criteria, including the quantity limit, and if so, document that determination and maintain good records regarding the shipment and return of custom devices. Although the proposed report format and content for patient-centric and physician-centric custom devices varies slightly, both types of annual reports should contain much of the same information, in the following three sections: [12]

(1) Section 1 should explain how each custom device supplied within the reporting year satisfies each element of the custom device exemption. This section should include attestations that each device meets each of the seven elements of the custom device exemption and, for some elements, a written explanation of how the device meets the requirement;

(2) Section 2 should contain a summary of custom devices shipped to, used, and returned by physicians or dentists during the reporting period, including the name or description, classification regulation, and

product code for each device. The summary should include the numbers of each type of device that were shipped, used/implanted, and/or returned to the manufacturer and can be provided in tabular format, as shown in Appendix I of the draft guidance; and

(3) Section 3 should contain details on custom device use, including the number of custom devices sold, used, and/or returned, including any applicable product name, brand name, model number, catalog number, product code, and classification regulation for each. This may include information that manufacturers do not currently collect. Specifically, for patient-centric devices, FDA expects information about each patient, including patient identifiers (initials/name, age), the date of the procedure, and a description of the patient's condition. This information can be provided in tabular format, as shown in Appendix I of the draft guidance.

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King & Spalding will continue to monitor FDA's interpretation and implementation of the custom device exception. We are happy to help determine how the draft guidance will apply to your custom devices or to assist you in drafting comments about the draft guidance.

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[1] 79 Federal Register 2446 (Jan. 14, 2014). The draft guidance, "Custom Device Exemption: Draft Guidance for Industry and Food and Drug Administration Staff," is available for download at **http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM380497.pdf** [hereinafter "Draft Guidance"].
[2] Draft Guidance at pages 2–3.
[3] *Id.* at page 3.
[4] *Id.* at page 2.
[5] *Id.*
[6] *See* Draft Guidance at pages 3–4.
[7] *See id*. at page 4.
[8] *Id*. at page 6.
[9] *Id.* at page 8.
[10] *Id.* at page 9.
[11] *Id.*
[12] *Id.* at pages 10–14.