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Client Alert

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FDA Requests Comments on the Custom Medical Device Exemption

On November 19, 2012, the Food and Drug Administration (FDA) issued a *Federal Register* notice indicating that it is currently drafting a policy to implement the custom device exemption requirements in the Federal Food, Drug, & Cosmetic Act (FDC Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), enacted on July 9, 2012.[1]

It is also seeking comments, due by January 18, 2013, on the appropriate uses of the exemption. The agency notes there will be a second opportunity to comment once a draft guidance is issued.

Background

Unlike most medical devices that require prior marketing authorization, if certain conditions are met, devices may be exempted. 21 U.S.C. § 360(j)(b). FDA is now developing a policy on this exemption in light of FDASIA, which requires qualifying devices to meet the following criteria:

1. it is created or modified in order to comply with the order of an individual physician, dentist, or other "specially qualified person."
2. it is not "generally available" in the United States in finished form through labeling or advertising by the manufacturer, importer, or distributor for commercial distribution;
3. it is "intended" to treat a "unique pathology or physiological condition" that no other device is available in the United States to treat;
4. it is "intended" to meet the special needs of a physician, dentist, or other specially qualified person, in the course of this individual's professional practice, or is intended for use by a patient designated in this individual's order;
5. no more than five units per year of the particular type of device are produced; and
6. the device manufacturer must submit an annual report to FDA explaining its use of the custom device exemption.

1 77 Fed. Reg. 69,488 (Nov. 19, 2012).

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FDA is requesting information concerning:

1. patient, manufacturer, dentist, or physician input on the appropriate use of the exemption;
2. specific examples when manufacturers, dentists, or physicians have used, would have liked to use, or plan to use the exemption to treat a "sufficiently rare condition;"
3. product areas other than orthopedic and dental devices where the exemption may be useful;
4. the information that manufacturers intend to require a physician, dentist, or other qualified person to submit to them when ordering a custom device; and
5. how often a custom device is ordered due to the individual physician or dentist's unusual anatomical features, or due to a unique need in the individual physician or dentist's practice.