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Alert | Health Care & FDA Practice

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FDA Releases Guidance for Final Rule Regulating Laboratory Developed Tests

On June 25, 2024, the U.S. Food and Drug Administration (FDA) released the final guidance document, Laboratory Developed Tests: Small Entity Compliance Guide (LDT Final Guidance), which aims to assist businesses of all sizes in complying with FDA regulations for in vitro diagnostic tests (IVDs), including laboratory developed tests (LDTs), as amended by the LDT Final Rule.[1]

Pursuant to the LDT Final Rule, FDA will gradually phase out its general enforcement discretion for most LDTs, which means that IVDs manufactured by laboratories will generally be required to meet all FDA device compliance requirements. In addition to setting out the timeline of the phaseout policy in a chart organized by IVD type, the LDT Final Guidance also provides a description and additional FDA resources for each compliance requirement applicable to IVDs.

This GT Alert summarizes the LDT Final Guidance and shares links to the FDA resources.

Requirements Related to Complaints, Medical Device Reports, and Correction and Removal Reports

FDA requires device manufacturers to document, investigate, and maintain files for all complaints they receive about their medical devices. FDA also requires manufacturers to submit a medical device report

[1] See GT Alert on the LDT Final Rule.

when they become aware of a reportable event (i.e., the event reasonably suggests the device may have caused or is likely to cause a death or significant injury). Finally, manufacturers must report the correction or removal of a device if it poses a health risk. See Complaint Files (presentation), Medical Device Reporting for Manufacturers, Guidance for Industry and Food and Drug Administration Staff, and Recalls, Corrections and Removals (Devices).

Registration and Listing Requirements

Owners or operators of establishments involved in producing and distributing medical devices intended for use in the United States are generally required to register annually with FDA, list every device made at the establishment, and describe all activities performed there. See Blood Establishment Registration and Product Listing and Device Registration and Listing.

Device Labeling Requirements

IVDs are exempt from most general labeling requirements if compliant with the unique device identification requirements at 21 CFR part 801 and the specific IVD labeling requirements at 21 CFR 809.10. See Device Labeling and In Vitro Diagnostic Device Labeling Requirements.

Investigational Use Requirements

An approved investigational device exemption (IDE) allows a device to be shipped for use in clinical research without complying with other requirements of the Federal Food, Drug and Cosmetic Act (FD&C Act). Investigations of diagnostic devices are exempt from most IDE requirements, provided they meet certain labeling requirements and the testing (i) is noninvasive, (ii) does not require an invasive sampling procedure that presents significant risk, (iii) does not introduce energy into a subject, and (iv) is not used as a diagnostic procedure without confirmation of the diagnosis. See Investigational Device Exemptions and In Vitro Diagnostic Device Studies Frequently Asked Questions.

Quality System Requirements

Manufacturers must establish and follow a quality system (QS) to ensure their devices are safe and effective. The QS requirements for medical devices, also known as current good manufacturing practices (CGMPs), are found at 21 CFR part 820. See QS Regulation/Medical Device Current Good Manufacturing Practices (CGMP).

Premarket Review Requirements

For most medical devices, the appropriate premarket submission type is based on the device classification. Moderate-risk (Class II) and some low-risk (Class I) devices are typically reviewed under a premarket notification pursuant to section 510(k) of the FD&C Act, or when no predicate device is available, under a de novo classification request pursuant to section 513(f)(2). Manufacturers of higher risk (Class III) devices may submit an application for premarket approval under section 515. See Premarket Submissions: Selecting and Preparing the Correct Submission.

Takeaways

LDT manufacturers should closely evaluate the potential impact of the LDT Final Rule, especially the phaseout policy. The LDT Final Guidance can be a helpful guide for LDT manufacturers in understanding the compliance requirements that may apply to their products at different points in the phaseout policy.

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Authors

This GT Alert was prepared by:

- Nicholas J. Diamond ‡ | +1 713.374.3557 | Nick.Diamond@gtlaw.com
- Charles C. Dunham, IV | +1 713.374.3555 | dunhamc@gtlaw.com
- Nicole Galli Baptista | +1 202.530.8543 | Nicole.Baptista@gtlaw.com

‡ *Admitted in the District of Columbia. Not admitted in Texas. Practice in Texas limited to federal FDA, FTC, and USDA and proceedings before federal agencies.*

Albany. Amsterdam. Atlanta. Austin. Berlin.¬ Boston. Charlotte. Chicago. Dallas. Delaware. Denver. Fort Lauderdale. Houston. Kingdom of Saudi Arabia.« Las Vegas. London.* Long Island. Los Angeles. Mexico City.+ Miami. Milan.» Minneapolis. New Jersey. New York. Northern Virginia. Orange County. Orlando. Philadelphia. Phoenix. Portland. Sacramento. Salt Lake City. San Diego. San Francisco. Seoul.∞ Shanghai. Silicon Valley. Singapore.⁻ Tallahassee. Tampa. Tel Aviv.^ Tokyo.¤ United Arab Emirates.‹ Warsaw.~ Washington, D.C.. West Palm Beach. Westchester County.