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White Paper: FDA Final Rule May 2024

By James Blackwell, President, Windshire Group, LLC and Labshire, LLC

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As we anticipated and reported in February, the FDA issued a final rule amending its regulations to state explicitly that in vitro diagnostic products (IVDs) fall under the Federal Food, Drug, and Cosmetics Act (FD&C Act) even if the manufacturer is a laboratory. In connection with amending the regulation, the FDA is phasing out its general enforcement discretion approach for LDTs so that IVDs manufactured by a laboratory will generally fall under the same enforcement approach as other IVDs.

The FDA cites patient safety as the primary motivation for the rule change. Due to technological advancements and changes in the LDT landscape since the FD&C Act was amended by the Medical Device Amendments of 1976 (MDA), the FDA believes LDTs result in greater risk to patients than before and thus warrant an updated approach. The changes the FDA cites include:

- Increased reliance on high-tech or complex instrumentation and software to generate results and clinical interpretations;
- Frequent use in laboratories outside the patient's healthcare setting;
- Frequent nationwide use;
- Manufacturing with instruments or components not legally marketed for clinical use
- Frequent use to inform or direct critical treatment decisions, widely screen for diseases, predict personal risks of developing certain diseases, and to diagnose serious medical conditions such as cancer and heart disease; and
- Increased reliance on high-tech instrumentation and software that puts patient medical data at risk.

While this groundbreaking rule is being implemented to enhance patient safety and benefit public health outcomes, it will have extensive impact on the laboratory industry. Under the enforcement discretion policy, the FDA generally has not enforced requirements related to registration and listing, adverse event reporting, current good manufacturing practices (CGMPs), or premarket review. The included phase out of this policy outlines a five-stage four-year process for organizations to come into compliance under the new rule. The phase out schedule five stages:

• *Stage 1:* 1 year after the publication date of the final rule, FDA expects compliance with MDR requirements, correction and removal reporting requirements, and QS requirements under § 820.198 (complaint files).

• *Stage 2:* 2 years after the publication date of the final rule, FDA expects compliance with requirements not covered during other stages of the phaseout policy, including registration and listing requirements, labeling requirements, and investigational use requirements.

• *Stage 3:* 3 years after the publication date of the final rule, FDA will expect compliance with QS requirements under part 820.

• *Stage 4:* 3 1/2 years after the publication date of the final rule, FDA expects compliance with premarket review requirements for high-risk IVDs offered as LDTs

• *Stage 5:* 4 years after the publication date of the final rule, FDA expects compliance with premarket review requirements for moderate-risk and low-risk IVDs offered as LDTs

This rule change is incredibly broad and brings substantial uncertainty along with a set of complex challenges to the laboratory industry. These uncertainties will drive what happens in the future regarding virtually every aspect of the laboratory field.

Preparing for rule compliance requires proactive steps, collaboration, and a thorough understanding of the proposed changes. Impacted institutions should start early, assess their LDTs, and align with FDA expectations to ensure patient safety and accurate test results. We think it wise to educate teams about the proposed rule and its implications, then do a broad assessment of existing LDTs to understand risk levels.

A gap assessment to identify areas where LDTs may not meet FDA requirements, and a quality system review will help prioritize next steps and create a strategic, cost-efficient compliance plan. The plan should include updated processes to align with FDA expectations, implementation of robust quality control measures, staff training, and submission readiness. Institutions may benefit from hiring outside experts, collaborating with their peers, and adopting best practices from compliant institutions.

You can count on Labshire's (https://labshire.com) recognized thought leaders to continue to monitor and assess the impact of this rule change. If Labshire can be of any assistance, we'd love to hear from you!

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Paul$Revere

Labshire.com | info@labshire.com

One Broadway, 14th Floor, Cambridge, MA 02142 I 1-844-686-5750