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The U.S. Food and Drug Administration issued a draft guidance today describing its intent to exercise enforcement discretion with respect to the premarket notification requirements for certain in vitro diagnostic and radiology devices with well-established safety and effectiveness profiles.

The draft guidance lists 30 different device types, including common urine and blood tests, alcohol breath tests, blood clotting protein tests, and radiology device accessories, such as film cassettes, film processors, and digitizers. FDA intends to exempt these devices from premarket notification requirements through the appropriate regulatory processes. In the meantime, however, FDA does not intend to enforce the premarket notification requirements with respect to these devices provided that they do not exceed the limitations on exemption specified in the device classification regulations.

FDA intends to continue to enforce all other applicable requirements, including, but not limited to, registration and listing and Good Manufacturing Practices as set forth in the Quality System regulations.

“The safety and effectiveness of these devices have been well demonstrated over the years,” said Jeffrey Shuren, M.D., director of FDA’s Center for Devices and Radiological Health. “By addressing the risk level of these devices, the agency is taking a smart regulatory approach that eases unnecessary requirements for manufacturers, while making sure the public has safe and effective devices.”

The device types listed in the draft guidance include devices identified by the FDA as those for which less stringent oversight would not compromise public health.

The FDA is seeking further comment on the draft guidance from manufacturing, clinical and patient communities. The draft guidance is open for comment for 90 days.

In the future, the FDA also intends to reduce the pre-market regulatory burden on additional in vitro diagnostic and radiology device types.

For more information:

FDA: Enforcement Policy for Premarket Notification Requirements for Certain In Vitro Diagnostic and Radiology Devices [2]

FDA: Medical Devices
[3]

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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