Rescission of Guidances and Other Informal Issuances Con Premarket Review of Laboratory Developed Tests

The Trump Administration is committed to combating COVID-19, to ensuring that the protected against future pandemics, and to keeping duplicative regulations and unne interfering with those efforts. Consistent with the President's direction in Executive C (Executive Order on Reducing Regulation and Controlling Regulatory Costs) and 13 on Regulatory Relief to Support Economic Recovery), and as part of HHS's ongoing review of regulatory flexibilities enacted since the start of COVID-19, the departmen the Food and Drug Administration ("FDA") will not require premarket review of labor ("LDT") absent notice-and-comment rulemaking, as opposed to through guidance d manuals, website statements, or other informal issuances. Those seeking approval emergency use authorization ("EUA") for an LDT may nonetheless voluntarily subm approval application, premarket notification or an EUA request, respectively, but are and FDA will adjudicate those submissions. Those opting to use LDTs in their labora premarket review or authorization may do so with the understanding that they would PREP Act coverage absent approval, clearance or authorization and would remain s by the Centers for Medicare & Medicaid Services under the Clinical Laboratory Impr Amendments of 1988, 42 U.S.C. § 263a, and its implementing regulations at 42 C.F an active EUA to use an LDT to detect the virus causing COVID-19 or its antibodies announcement.

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