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QUOTED. Feb. 8, 2019. Scott Gottlieb.

by

US FDA plans to take both formal and informal approaches to reviewing device applications and is willing to accept existing and post-market data, outside-of-the US data and case histories in reviewing device submissions, it says in a final "least burdensome" guidance. See what agency head Scott Gottlieb said about it here.

"The guiding principles outlined explain our approach to assuring we obtain the minimum information needed ... without compromising our stringent review standards, our gold standard for assuring safety, or the scientific integrity of our decision-making process." –Scott Gottlieb, commissioner, US FDA

- Find out more: *US FDA Emphasizes Computer Modeling, Existing Data For Least-Burdensome Device Submissions*

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