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FDA Publishes a Wide Range of Guidances in the Final Days of the Biden Administration

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On January 6 and 7, 2025, the FDA announced, by our count, 31 draft or final guidances, on a wide range of topics. Historically, an incoming administration will impose a temporary freeze on the issuance of guidances and rules, and might ultimately have different policy priorities and goals than the previous administration. Thus, the release of these numerous new guidances reflects topics that the FDA likely views as particularly important to address.

The guidances span a variety of areas across the FDA, with guidances being issued for every regulated product area. Guidance topics include draft guidance aimed at helping to improve the accuracy and performance of pulse oximeters across skin tones; draft guidance for developers of artificial intelligence (AI)-enabled medical devices; draft guidance on including tissue biopsies in clinical trials; draft guidance regarding accelerated approval and consideration for determining whether a confirmatory trial is underway; final guidance on levels for lead in processed baby food; and draft guidance on the study of sex differences in clinical evaluation of medical products.

Guidances are non-binding by nature, and the draft guidances would still need to be finalized. Nevertheless, these guidances provide important insights into the FDA's thinking on a number of evolving regulatory issues.

Akin will be posting selectively about the recently released guidances in the coming days.

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