



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

January 7, 2025

Reading Time : **1 min**

By: Nathan A. Brown, Maddy L. Bolger

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 Guidance topics include draft guidance aimed at helping to improve the accuracy and performance of pulse oximeters across skin tones; draft guidance for developers of artificial intelligence (AI)-enabled medical devices; draft guidance on including tissue biopsies in clinical trials; draft guidance regarding accelerated approval and consideration for determining whether a confirmatory trial is underway; final guidance on levels for lead in processed baby food; and draft guidance on the study of sex differences in clinical evaluation of medical products.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

## Categories



© 2025 Akin Gump Strauss Hauer & Feld LLP. All rights reserved. Attorney advertising. This document is distributed for informational use only; it does not constitute legal advice and should not be used as such. Prior results do not guarantee a similar outcome. Akin is the practicing name of Akin Gump LLP, a New York limited liability partnership authorized and regulated by the Solicitors Regulation Authority under number 267321. A list of the partners is available for inspection at Eighth Floor, Ten Bishops Square, London E1 6EG. For more information about Akin Gump LLP, Akin Gump Strauss Hauer & Feld LLP and other associated entities under which the Akin Gump network operates worldwide, please see our Legal Notices page.