



FDA Clarifies Its Approach to Prescription Drug Use-Related Software

October 28, 2026

Reading Time : **1 min**

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The United States Food and Drug Administration (FDA) has released final guidance clarifying how its drug labeling requirements apply to certain software outputs used with prescription drug products and drug-device combination products, including companion applications. The guidance follows FDA's draft guidance from September 2023, along with a 2018 Federal Register notice seeking public comment on the topic, which provides a more defined framework for determining when software outputs are FDA-required labeling or promotional labeling and whether the software should be described in the drug's Prescribing Information (PI). Among other changes from the draft guidance, FDA clarifies its treatment of standalone software, adds a labeling decision tree and illustrative examples, and recommends that labeling specify when associated software is not necessary for safe and effective use. The final guidance highlights the importance of early regulatory planning for drug sponsors that offer or plan to offer companion software, and for digital health developers, particularly where sponsors intend to support software-related claims with clinical evidence.

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