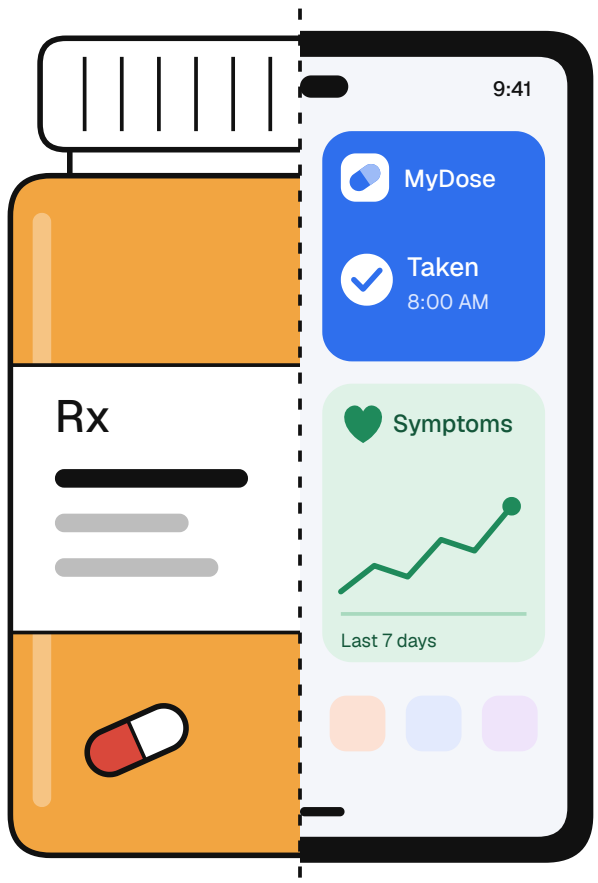
FDA · PDURS final guidance · Oct 2026 Swipe →



Companion apps could become part of ClinDev strategy.

What FDA's final guidance on prescription drug use-related software means for clinical developers.

Abhi Pratap · Personal views

Drafted with AI · curated by hand

Two kinds of labeling

Applies to any app a drug sponsor, or a partner on its behalf, provides for use with its drug.

	FDA-required	Promotional · default
Where	In the drug's label	In the app, filed with FDA on Form 2253
Entry	The app is essential, or a trial shows it improves a clinical outcome	No outcome trial needed
Updates	Certain changes reviewed by FDA as labeling changes	Ship, then file what users see
Value	A labeled claim others would need their own study to make	Speed and control. Accurate, balanced content earns trust and could help sponsors understand patient journeys

Both can be sound strategies. Evidence largely decides which one applies.

A claim that's hard to replicate.

Randomize the drug plus the app against the drug alone. If the app improves a clinical outcome or validated surrogate, the result can be described in the Clinical Studies section of the label.

This applies to standalone apps too. FDA's own example: a diabetes app with reminders and coaching, measured on HbA1c.

A similar app can be built. The labeled claim needs its own evidence.

Potential differentiation

Pair your inhaler or autoinjector with an app, and the drug's label can say so, even without outcome data. FDA notes this may help prescribers tell apart products with connected software from those without.

Upside	Could inform formulary and prescribing conversations
Caveat	The mention comes with a line: the app is not necessary for safe and effective use

A new chapter for an established brand.

Outcome data for an app could support a new labeling claim, added after approval through a supplement.

For payers	A labeled result such as lower HbA1c is likely to carry more weight than app engagement numbers such as daily logins
Untested	How generics and biosimilars handle a drug-plus-app claim. The guidance refers to existing frameworks and "permissible differences" in interface.

More flexible routes to the evidence.

Adequate and well-controlled studies can incorporate real-world data, as appropriate. Depending on the program, evidence for the app might come from:

- A pragmatic trial
- A decentralized trial
- An add-on arm inside a broader program

Not necessarily a standalone pivotal study.

Clearer guidance to plan around.

01 A decision tree for labeling

02 A defined "by or on behalf of" a sponsor

03 A dedicated PDURS type on Form FDA 2253

04 Sample label wording

Together, these make it easier to plan an app strategy with confidence.

Some practical questions to work through.

Drug development and software development often run on different timelines. Bringing them together takes some planning.

Development	Software tends to iterate in weeks, while drug programs plan over years. Aligning the two early can help.
Deployment	Apps run on phones, app stores and operating systems that change on their own schedules.
Lifecycle	Updates users can see are filed with FDA, and some changes to a labeled app may need review. Release planning can account for this.
Ownership	Clear ownership after launch helps, whether with medical, commercial, IT or a partner working on the sponsor's behalf.

Thinking about these early can make the path smoother.

These are early views. The topic needs more voices.

What PDURS means in practice will depend on perspectives I don't have alone:

- Clinical development
- Regulatory
- Patients and families
- Payers

What am I missing? Tell me in the comments.

Source: FDA, Regulatory Considerations for Prescription Drug Use-Related Software, final guidance, Oct 2026. Views are my own.