UPDATES

Health notices · Saturday 7 November

3 notices from the agencies today, in plain words, each with the original linked.

Cinacalcet tablets recalled for failed dissolution testing

FDA · Recall

If you take cinacalcet tablets, this FDA Class II recall affects certain 30 mg, 30-count bottles (Rx only) distributed in the US.

The issue reported is failed dissolution specifications, meaning the tablets did not meet the required testing standards before release.

Check whether your bottle matches the affected product details in the recall listing, and stop using it if it is identified as part of the recall.

Read the original notice

FDA approval of glipizide and metformin hydrochloride tablets

FDA · Approval

If you have type 2 diabetes, the FDA has approved glipizide and metformin hydrochloride tablets (taken by mouth) as an adjunct to diet and exercise.

"Glycemic control" means keeping your blood sugar in a better target range, so diabetes can be managed more effectively.

This approval may matter if you and your clinician are considering a treatment that combines these medicines for adults with type 2 diabetes.

Read the original notice

FDA approval for fulvestrant injection for certain advanced breast cancers

FDA · Approval

If you're a postmenopausal person with hormone receptor (HR)-positive, HER2-negative advanced breast cancer, the FDA has approved fulvestrant injection as a treatment option. HR-positive means cancer that uses hormone signals to grow.

The approval also covers people whose disease has progressed after endocrine therapy (hormone-blocking treatment), and people using it with other medicines named in the label.

It may matter to you tomorrow because it gives clinicians an additional FDA-approved option for treating your type of advanced breast cancer.

There aren't any patient actions listed in the notice itself.

Read the original notice

Where this comes from

- Cinacalcet tablets recalled for failed dissolution testing

  US Food and Drug Administration - enforcement report · https://www.fda.gov/drugs/drug-safety-and-availability/drug-recalls
- FDA approval of glipizide and metformin hydrochloride tablets

  US Food and Drug Administration - Drugs@FDA · https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=078083
- FDA approval for fulvestrant injection for certain advanced breast cancers

  US Food and Drug Administration - Drugs@FDA · https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=216722