PHARM TECH BASICS · ONE-PAGER

Recalls, REMS, Medication Guides and Reporting

FDA recall classes with real examples, what the pharmacy does with a recall notice, REMS programs, when a Medication Guide must be given, MedWatch and VAERS, and Orange Book and Purple Book ratings

48 sources + more detail

pharmtechbasics.com/sheets/pharm-fda-recalls-rems.html

checked Nov 2026

1 Recall classes (21 CFR 7.3)

TYPE	MEANING	REAL EXAMPLE (FDA ENFORCEMENT REPORT)
Class I	Reasonable probability of serious harm or death; usually reaches the patient (consumer) level	Clonazepam ODT 0.125 mg cartons printed with the wrong strength (2025)
Class II	Temporary or medically reversible harm, or serious harm is remote; usually retail level	Levothyroxine 200 mcg tablets found subpotent (2026)
Class III	Not likely to cause harm; usually wholesale level	Toothpaste tube labeled with the wrong flavor (2025)
Market withdrawal	Minor violation FDA would not act on, or no violation	Tampering with no sign of a manufacturing problem (FDA's example)
Safety alert	FDA notice of a new risk or recall (MedWatch alerts)	Posted on FDA.gov and sent by email to subscribers

EXAM TIP Class I is the most dangerous. The class ranks the hazard, not the reason: subpotent tablets were Class II for levothyroxine but Class III for buspirone. FDA assigns the class; the firm runs the recall.

2 When a recall notice arrives

1. Read the notice: product, NDC, lot (or serial) numbers, depth, and what to do.
2. Search everywhere: shelves, refrigerator, will-call, robots and automated cabinets, returns bin.
3. Pull every match, label it 'Recalled: do not dispense' and quarantine it away from saleable stock.
4. Return or destroy as the notice says, and send the response form even if you found none.
5. Record what was found, pulled and returned.
6. Patient-level recall: give the pharmacist a dispensing report by NDC (and lot, if recorded). The pharmacist decides who is contacted and what they are told.

SAFETY Never tell a patient to stop a recalled medicine. For Class II and III recalls FDA says patients can usually keep taking it, and stopping some drugs is more dangerous than continuing. Send the question to the pharmacist.

3 REMS (Risk Evaluation and Mitigation Strategy)

A safety program FDA requires for a few drugs with a serious risk, on top of the label. It can include a Medication Guide, a communication plan, elements to assure safe use (ETASU) and an implementation system. ETASU are the hard stops: certified prescribers, certified pharmacies, use only in certain settings, proof of a safe-use condition (such as a negative pregnancy test), monitoring, or a registry.

PROGRAM	RISK	WHAT THE PHARMACY DOES
Isotretinoin iPLEDGE	Birth defects	Certified pharmacy; authorization number for every fill; 30-day supply at most; no refills; for a patient who can get pregnant, not after the REMS date
TIRF (transmucosal immediate-release fentanyl)	Overdose if not opioid tolerant	Certified pharmacy; authorization confirms enrollment and opioid tolerance; Medication Guide each fill
Spravato (esketamine)	Sedation, dissociation, respiratory depression, misuse	Ships only to certified settings; patient watched at least 2 hours
Zyprexa Relprevv (olanzapine injection)	Post-injection delirium sedation	Given only in certified facilities that watch the patient at least 3 hours
Clozapine	Severe neutropenia	REMS ended in 2025: no REMS check or ANC report before dispensing; ANC monitoring per label continues

EXAM TIP No authorization, no fill: if the REMS check fails, the prescription goes to the pharmacist. Generics of a REMS drug must have a REMS too. OTC drugs never have one.

4 Medication Guides (21 CFR 208)

FDA-approved handouts for drugs with serious risks, when the information could prevent serious harm or change the decision to take the drug, or when adherence is crucial. Examples: sertraline (Zoloft), celecoxib (Celebrex), warfarin, montelukast (Singulair), Adderall XR. The stock label says to dispense one.

SETTING	GIVE THE MEDICATION GUIDE
Community, mail-order or hospital outpatient pharmacy (patient takes it home)	Every new fill and every refill
Clinic, infusion center or ED (a health professional gives the drug)	First dispensing, after a material change, or on request
Inpatient, including nursing homes	On request (FDA does not enforce routine handouts)
Any setting	Whenever the patient asks, and as a REMS requires

Paper by default, electronic if the patient asks. A prescriber may direct that a patient not get one, but the pharmacy must still give it if the patient asks. Patient package inserts must go with every fill of oral contraceptives and estrogens.

5 Reporting problems

SYSTEM	WHAT GOES THERE	HOW
MedWatch (FDA)	Serious reactions, quality problems, therapeutic failure, use errors: drugs, biologics, devices, supplements	Online; Form 3500 (professionals), 3500B (patients); 3500A is mandatory (makers, user facilities)
VAERS (CDC and FDA)	Any adverse event after a vaccine; providers must report listed events	Online at vaers.hhs.gov
FAERS (now AEMS)	FDA's database of drug and biologic reports	Fed by MedWatch and manufacturer reports

EXAM TIP Vaccine reaction: VAERS. Drug, device or product problem: MedWatch. A technician who hears of a reaction tells the pharmacist; anyone may file a report.

6 Orange Book and Purple Book

ORANGE BOOK CODE	MEANING
AA, AN, AO, AP, AT	Therapeutically equivalent; no known bioequivalence problem (letter 2 = dosage form)
AB, AB1, AB2…	Equivalent once bioequivalence was shown; AB1 matches only AB1
B codes (BC, BD, BX, B*…)	Not rated equivalent at this time
No code	Single-source product

Orange Book: FDA-approved drugs with therapeutic equivalence ratings. Equivalent means same active ingredient, amount, dosage form and route, and bioequivalent. Purple Book: FDA-licensed biologics. A biosimilar has no clinically meaningful difference from its reference product; an interchangeable biosimilar (such as Semglee, insulin glargine-yfgn) may be substituted without calling the prescriber where state law allows.

SAFETY A different salt, or IR versus ER, is never AB. The Orange Book rates; state law decides substitution, and the pharmacist makes the call.

MORE More real recall examples

CLASS	PRODUCT AND REASON (RECALL NUMBER)
I	Prograf (tacrolimus) 0.5 mg: bottles may contain empty capsules (D-0211-2025)
I	Systane Ultra PF eye drop vials: not sterile (D-0200-2025)
I	Udenyca (pegfilgrastim-cbqv) syringes: specific serial numbers stored at room temperature instead of the refrigerator; recall started by the distributor, McKesson (D-0353-2026)
II	Glipizide ER 2.5 mg unit dose: failed dissolution (D-0202-2025)
II	Bisoprolol/HCTZ 2.5/6.25 mg: nitrosamine impurity above its limit (D-0301-2026)
III	Buspirone 5 mg: subpotent (D-0511-2026)
III	Trokendi XR (topiramate ER) 25 mg: failed dissolution (D-0758-2026)

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