



Americas · Medicines, tobacco, alcohol

United States

Prescription drugs are serialised and traced at package level under DSCSA. Large dispensers had to comply by 27 November 2025; small pharmacies have an exemption to 27 November 2027. The FDA food traceability rule (FSMA 204) requires lot-level records on high-risk foods from 20 July 2028 but does not require a code on pack. GS1 US runs the Sunrise 2027 programme for 2D codes at the checkout.

THE REGIME

SYSTEM	DSCSA (prescription drugs); FSMA 204 (food records, no code mandate)
CODE ON THE PRODUCT	GS1 DataMatrix with GTIN, serial, lot, expiry on prescription drugs
AGGREGATION	DSCSA does not require it; most of the supply chain uses aggregated case data anyway.

STEPS FOR A SUPPLIER

- ☐ Register your products and GTINs in the national system: DSCSA.
- ☐ Print a unique serialised code on every saleable pack.
- ☐ Verify every code on the line; aggregate into cases and pallets where required.
- ☐ Report production and shipments to the national system.

ON THE LINE, BEFORE THE FIRST SHIPMENT

- ☐ The data in the code is agreed: GTIN, serial number, batch, expiry date or crypto tail, as the rules for your product group require.

- ☐ A verifier has graded printed samples (ISO/IEC 15415 for 2D codes) before the first shipment.

- ☐ A camera after the printer reads every code at line speed, and packs with an unreadable code are rejected.

- ☐ Records show which code went on which pack, case and pallet, ready for the report to the system.

DATES AHEAD

27 Nov 2027	End of the small dispenser exemption
31 Dec 2027	GS1 US Sunrise 2027: retail checkouts able to scan 2D (industry target with no legal force)
20 Jul 2028	FSMA 204 food traceability records (enforcement date)

SOURCES

1. FDA: DSCSA exemptions: <https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/exemptions-under-drug-supply-chain-security-act>
2. FDA: Food Traceability Rule: <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-requirements-additional-traceability-records-certain-foods>
3. Forbes: barcode being replaced by 2027: <https://www.forbes.com/councils/forbesbusinesscouncil/2026/09/24/after-50-years-the-barcode-is-being-replaced-is-your-brand-ready-for-2027/>

Current version and all sources:
2dtracker.com/country/usa.html

Typical steps. This is not legal advice: check the regulation itself.