# Executive Summary

## FDA Enforcement Now Includes Med Spas

### How This Change Affects Your Practice

**What changed:** The Drug Supply Chain Security Act (DSCSA) is now being enforced at the medical practice level. Any practice that purchases, stores, or administers drug products in-office is now subject to FDA supply chain compliance inspections — not just manufacturers, wholesale distributors, and pharmacies.

### The Drug Products at Issue in Med Spa & Aesthetics Practices

If your practice purchases and administers any of the following, federal drug supply chain requirements apply to you — regardless of whether you operate a pharmacy:

**Injectable & Aesthetic Treatments**

- Neurotoxins (Botox, Dysport, Xeomin, Daxxify)
- Dermal fillers (Juvéderm, Restylane, Sculptra)
- Kybella (deoxycholic acid)
- Platelet-rich plasma (PRP) therapies

**Specialty & Emerging Products**

- Weight loss medications (GLP-1s: semaglutide, tirzepatide)
- Prescription-strength retinoids
- Prescription-strength hydroquinone
- Eyelash enhancers (Latisse / bimatoprost)
- Peptide therapies (Ipamorelin, BPC-157, Sermorelin)

### Why Enforcement Has Reached Med Spas

The DSCSA, enacted in 2013, was implemented in phases. For nearly a decade, enforcement focused on manufacturers, wholesalers, and national serialization systems. With those controls now in place, regulatory focus has shifted downstream to the final point in the supply chain: the practice itself.

> ***The proof point:*** *In January 2026, the FDA issued its first publicly documented inspection finding against a physician-owned aesthetics practice — a med spa in Texas — for failures in how injectable drug products were purchased, tracked, and documented. FDA investigators cross-referenced what the practice administered to patients against manufacturer shipment records. The gap was large enough to trigger a formal citation.*

These inspections are unannounced, data-driven, and based on real documentation — not policy statements. Investigators evaluate whether a practice can prove, with records in hand, that every product it administered came from an authorized, identifiable source.

### What FDA Inspectors Now Evaluate

- ■ Purchasing only from federally authorized vendors
- ■ Documentation tying purchased product to administered product
- ■ Alignment between purchase invoices, inventory logs, and treatment records
- ■ Lot number and expiration date traceability
- ■ Written procedures for managing questionable or quarantined product
- ■ A defined, repeatable compliance process backed by written policies

## Where Practices Are Exposed

Most practices do not fail due to intent. They fail due to execution.

- Vendor credentials assumed to be valid but never formally verified
- Breaks between purchasing records and usage documentation
- No reconciliation between what was purchased and what was administered
- Informal or inconsistent recordkeeping across staff and locations
- No written procedure for suspect or compromised product
- Product movement between locations without traceable documentation

## The Claritas Axis Platform: Know Where You Stand

Most med spas that fail an FDA inspection didn't know they had a problem. The Claritas Axis assessment platform is built to surface exactly that — before an inspector does. Start free. See your risk score. The assessment does the rest.

TIER 1 **FREE**

### 10-Question Sample Assessment

*Your risk snapshot in under five minutes*

- Covers the highest-risk compliance areas
- Weighted scoring: Low Risk, Moderate, or High / Critical Exposure
- Critical override logic flags documentation and reconciliation failures
- Instant results — no sales call, no waiting

TIER 2 **$99**

### Full 81-Question Assessment + Gap Report

*The complete picture, delivered instantly*

- Covers all 10 FDA-evaluated operational areas
- ATP Registry section verifies every vendor you purchase from
- Personnel & Roles section identifies who owns each compliance function
- Detailed, practice-specific gap report — fully automated

Practices that complete the full assessment receive an instant gap report identifying every area of exposure — ranked by risk level — with a clear remediation path. No waiting for a consultant. No scheduled call. Your compliance picture, immediately.

### Start with the Full Assessment — $99

*81 questions. Instant gap report. No sales call. Start at claritasaxis.com*

## Bottom Line

**FDA enforcement now includes med spas and aesthetics practices.**

The question is not whether these requirements apply.

**The question is whether you find the gaps before the FDA does.**