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Medspas on Alert: The FDA Says You're a Dispenser Too

Key Takeaways

- Medspas and other entities operating in the aesthetic space that dispense or administer prescription drugs should assess whether they have obligations as dispensers under the DSCSA and ensure they have policies, procedures and controls in place to demonstrate compliance with applicable requirements.
- To avoid the deficiencies cited in the warning letter, dispensers should focus on strengthening supply chain controls, maintaining complete product records and ensuring operational readiness for FDA inspection.
- Dispensers that receive a Form FDA 483 documenting observations of potential violations after an FDA inspection should act immediately to develop a thorough response with supporting documentation.

On April 1, 2026, the FDA issued a warning letter to Pure Indulgence Aesthetics (Pure Indulgence), a Texas-based medical spa. Notably, this is the first warning letter issued to a "dispenser" of prescription drugs for violations of the Drug Supply Chain Security Act (DSCSA), showing that the FDA's enforcement activities extend beyond wholesale distributors and manufacturers, FDA's primary targets for DSCSA violations to date.

Medspas and other dispensers should proactively:

- Review their sources for FDA-regulated prescription drug products to ensure that they are only conducting business with authorized trading partners;
- Ensure product inventory is appropriately stored, labeled and tracked; and
- Review their facility's preparedness for an inspection by FDA or other regulators, including response protocols and procedures.

Background on the DSCSA

The DSCSA, enacted in 2013, is designed to improve the integrity of the prescription drug supply chain through requirements related to product tracing, product identification, verification and ensuring transactions are conducted with authorized trading partners. Under the DSCSA, there are different responsibilities for various trading partners within the supply chain, such as prescription drug manufacturers, repackagers, wholesale

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distributors, third-party logistics providers and dispensers. The DSCSA also authorizes the FDA to grant waivers, exceptions, or exemptions from certain requirements (e.g., certain temporary exemptions for small dispensers).

The Pure Indulgence Inspection and Warning Letter

To date, the FDA's discussion of DSCSA dispenser requirements has centered on pharmacies. However, the Pure Indulgence warning letter emphasizes that the definition of a dispenser includes any "person authorized to dispense or administer human prescription drugs." This expansive definition includes a medspa that employs individuals authorized to dispense and/or administer prescription drugs under a medical doctor's supervision.

The FDA identified several key issues arising from a December 2025 inspection and Pure Indulgence's subsequent response to the Form FDA 483 issued at the end of the inspection. In particular, the FDA focused on administration of Botox, alleging the following key concerns:

- **Use of unauthorized trading partners.** The facility did not demonstrate that it purchased Botox from authorized trading partners. The FDA noted a significant discrepancy between the volume of authentic Botox purchased from the manufacturer (an authorized trading partner) and the number of patients that received Botox based on facility records, leading to a conclusion that product was obtained from unauthorized sources.
- **Lack of product identifiers.** Pure Indulgence failed to ensure that each prescription drug it purchased had a required product identifier (a standardized graphic that includes specified information about the product, including a numerical identifier, in human and machine-readable form). FDA investigators collected an unlabeled vial during the inspection that was later confirmed to contain the active ingredient in Botox and for which the facility was unable to provide any label or packaging that had a product identifier.
- **Inadequacy of inspection response.** According to FDA, the facility's response to these deficiencies was inadequate to assure FDA of compliance moving forward.

Looking Ahead

Overall, the warning letter serves as a clear reminder that the FDA expects medspas that qualify as dispensers to meet DSCSA compliance standards. Informal practices or gaps in documentation, particularly involving products with significant risk, may expose providers to enforcement risk.

If you have questions about DSCSA compliance and related exceptions or exemptions, medspa best practices, or preparing for (or responding to) FDA inspections, please contact Ryan Thurber, Claire Davies, Laura Pone, Suzanne Bassett, Hiba Al-Ramahi or your regular Polsinelli attorney.