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THE FDA'S EVOLVING CBD CRACKDOWN — The FDA is broadening its focus when it comes to the CBD industry. Up until now, enforcement actions have been generally limited to producers who make egregious medical claims for ingestible products — cancer, AIDS, coronavirus and the like. The latest two warning letters target CBD topical producers, which the FDA inspected for current good manufacturing practice, or CGMP, compliance.

The details: The FDA warned Honest Globe for its Elixicure CBD products, which the company marketed as a pain reliever that could help everything from muscle strains to arthritis. The FDA outlined a range of CGMP violations and called out the company for labeling its products as "FDA registered," which "misleadingly implies that FDA has endorsed or approved the products in some manner."

BioLyte Laboratories also received a warning letter for CBD-containing topicals marketed for pain relief. While the company listed CBD as an "inactive ingredient" on its labels, "the labeling for these products clearly represent CBD as an active ingredient," the letter read. An FDA investigator found numerous CGMP violations, including lab testing failures and a lack of stability data to justify the products' shelf life.

The context: CBD is allowed in cosmetics products, but "there are other issues going on here," said Jonathan Havens, co-chair of Saul Ewing Arnstein & Lehr's cannabis practice. "It's not just that they had a CBD topical product."

Indeed, Elixicure issued a press release touting that its CBD product was "the very first, and currently only, over-the-counter (OTC) topical drug with [CBD] to be registered and certified [by the FDA] to date."

The agency said any such statements are inaccurate.

What the letters make clear, Havens explained, is that the agency is serious about topical products, too, especially ones that make therapeutic claims.

“Doing an inspection and calling attention to GMP violations is new in the [CBD] topical space,” Havens said. “But it's not so different from what we've heard from FDA previously” in terms of making therapeutic claims.