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Reacting to stakeholder complaints . . .

FDA To Cease Citing CGMP Violations For Traditional Pharmacists

FDA will no longer report when traditional compounders deviate from current good manufacturing practices after industry stakeholders pushed against the practice, saying the agency ignored congressional intent. Republican Rep. Buddy Carter (GA) and the International Academy of Compounding Pharmacists (IACP) found the move encouraging, but both want FDA to clarify how it determines when a compounder is a traditional pharmacy falling under the law's section 503A and thus exempt from FDA oversight.

Compounding pharmacies, and at least one lawmaker, had alleged that FDA was improperly inspecting traditional 503A pharmacies and citing them with CGMP violations, noting these pharmacies fall under state oversight and must instead meet USP standards. FDA agreed to back off a bit in a notice released Tuesday (July 12), saying it will continue to do inspections but generally won't cite 503A pharmacies with CGMP inspections.

Starting in August, FDA said, investigators will start making a preliminary determination if a compounder is compliant with certain conditions of 503A before closing an inspections. If compounders meet these requirements, FDA will not include violations under CGMP on the published Form FDA-483.

But FDA emphasized that while 503A compounders are exempt from specific parts of the Food, Drug and Cosmetic Act, such as CGMP requirements, they still are subject to a prohibition on "preparing, packing, or holding drugs under insanitary conditions." The FDA said inspectors will still note insanitary conditions on Form FDA-483 regardless of a 503A classification, the notice said.

The agency explained in the notice that FDA investigators had been identifying deviations from drug production practices on Forms FDA-483 that could lead to quality problems without regard to whether the observations relate to CGMP deficiencies or other deficiencies.

FDA said when determining whether to pursue regulatory action, the agency considered whether the compounder met the conditions of section 503A. "When FDA, has issued a warning letter, FDA has only cited compounders that were not registered as outsourcing facilities for violations of CGMP requirements when the agency had evidence that at least some of their drugs were not compounded in accordance with the conditions of section 503A," the notice says.

However, stakeholders told FDA they wanted inspectional evidence regarding section 503A to be reviewed earlier before the close of an inspection, and to be taken into consideration in decisions about what to include the violations in any Form FDA-483.

FDA said in the notice that if the agency's post-inspection review differs from the agency's preliminary assessment and reveals that a facility fails to compound in accordance with section 503A, FDA still intends to consider citing CGMP violations in any regulatory action it decides to pursue.

IACP said it is encouraged by the notice, but the group wants more clarification on what FDA will use to determine if a compounder counts as a 503A pharmacy. The group also took some credit for the agency's new stance.

"It should be noted — we rarely see a Federal agency publish this type of notification where they outline a course correction in their procedures without some sort of influence," the group said.

Carter agreed the move is encouraging, but also told *Inside Health Policy* that he still believes that state pharmacy boards should have control over small independent pharmacies.

"The recent announcement by the FDA on inspection standards for 503A pharmacies is encouraging and I am glad to see that the FDA is taking comments from stakeholders into consideration," Carter said. "While this announcement is a step in the right direction, I still have concerns that inspectors will be able to subjectively determine whether a pharmacy is a small compounding pharmacy or a large manufacturing facility. My hope is that the FDA will issue additional guidance in the near future that will define clear parameters under which inspectors should operate."

"FDA has historically taken note of any issues in the facilities," said Elizabeth Jungman, director of public health programs at the Pew Charitable Trusts. "Compounders have complained because there are observations on the public facing forms that aren't relevant."

IACP, as part of its recent lobbying, strongly challenged FDA's inspections of 503A compounding pharmacies using CGMPs instead of USP or other standards established by state pharmacy laws and regulations. The group specifically questioned: 1. why 483s based on CGMPs were published on FDA's website publicly, for all to see, even when FDA later

determined the pharmacy was in compliance with section 503A and handed the pharmacy investigation back to the state Board of Pharmacy, and 2. why FDA would not always give pharmacies copies of the 483 when they were leaving the inspection. “Essentially, pharmacies had to guess whether one would be issued and what would be in it,” IACP says on its website. — *David Lim*
