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Compliance Corner: Don’t Sign (Or Even Hear) That Affidavit!

by Shawn M. Schmitt

Device makers presented with an affidavit by the US FDA during a facility inspection should walk away as quickly as possible, King & Spalding partner Jessica Ringel advises.

If you’re presented with an affidavit by a US Food and Drug Administration investigator during a facility inspection, don’t sign it. In fact, don’t even listen to it being read aloud.

That’s advice from Jessica Ringel, a partner in the Washington, DC, office of law firm King & Spalding. She says device makers can land in hot water with the agency if they sign – or even hear – an affidavit, a written declaration typically made under oath.

“We absolutely recommend against signing affidavits. You should not sign one even if you’re feeling pressured to do so. In fact, you might not even want to hear or listen to the affidavit being read out loud. Sometimes you might just need to get up and walk out of the room,” she said.

Ringel explained why: “If the investigators read [the affidavit] to you, and you acknowledge it or you correct errors, or you don’t correct any errors … they could take [that] to mean that [because] you listened and therefore you’re aware of the terms, …[then] you must’ve agreed to either all of it or some of it – whatever you didn’t object to. And they might include that in their EIR [Establishment Inspection Report], now saying that you’ve agreed with the statement read.”

But beyond that, the agency doesn’t have any authority to dole out affidavits in relation to an inspection.

“FDA’s statutory authority for inspections and what it can do and request and review during inspections does not include the creation or signing of affidavits,” Ringel said. “It’s not an authority delegated to them by statute.”

"Just say no to affidavits." – Jessica Ringel

Further, she said, affidavits are often given with little or no notice, and the person receiving one typically doesn't have the time to adequately review it.

"There's also going to be little to no opportunity to revise anything in that affidavit," Ringel said. "So when you sign it, you're creating a legal document. You're affirming to the accuracy of the statements in that document, but you didn't prepare it. You probably didn't review it closely. Your legal counsel didn't review it, and it might not be fully accurate. So that's definitely not something we want to make official with a signature.

"And if there are inaccuracies in [the affidavit], it could be considered a false statement to the government, or there could be accidental legally binding admissions of noncompliance that you're agreeing to," she added. "Just say no to affidavits."

Ringel's comments came recently at King & Spalding's 14th Annual Medical Device Summit. Also speaking was Steve Niedelman, the law firm's quality systems and compliance consultant.

Niedelman, who worked at the FDA for 34 years in both its device center and Office of Regulatory Affairs, urged manufacturers to have a policy in place on how to handle affidavits before an investigator even knocks on their door.

"Make sure that FDA is aware of that policy at the beginning of the inspection so they don't think it's an ad hoc decision" if a company declines to sign an offered affidavit, he said.

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By Shawn M. Schmitt

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