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Can You Stop Photography During An FDA Inspection?

By **Katie Gates Calderon, Lindsey Heinz and Hillary Nicholas**

Law360, New York (September 1, 2017, 10:43 AM EDT) --
Regulatory attorneys are familiar with two pressing questions from clients faced with an inspection by the U.S. Food and Drug Administration: "Can the FDA investigator take photographs during the inspection?" and "What will happen if I try to stop or altogether prevent the inspector from taking photos?" As a rule, from suppliers to co-packers, entities in the food-supply chain do not relish the possibility of an FDA inspection, especially when an inspector arrives with camera equipment.

Katie Gates Calderon

In particular, companies are understandably concerned that inspection photos will capture proprietary aspects of their operations or that information obtained from the photographs may be used against them in court. Recently, the FDA issued a warning letter to a homeopathy company accusing the company of impeding the agency's investigation by refusing to permit the inspector to photograph a piece of equipment. While raised in the context of a different regulated industry, this warning letter has renewed familiar concerns from many of our food industry clients — just what are a company's rights in this situation? Does the FDA have the authority to photograph or record in a company's facility? Can a company refuse to allow photography? Should a company prevent photographs if it can?

Lindsey Heinz

The Scope of — and Limitations on — FDA's Authority

On Aug. 2, 2017, the FDA issued a warning letter to Homeolab USA Inc., part of a Canadian homeopathy company called Homeocan Inc., that produces homeopathic products and medicines. The FDA's letter stems from its January 2017 inspection of Homeolab in which the inspector was allegedly prevented from photographing "excess material clinging to the sides" of certain pieces of equipment relevant to its investigation.[1] In its warning letter, the FDA repeated an all-too-familiar refrain: The company "impeded the inspection by preventing [the FDA's] investigator from photographing this piece of equipment."[2] But while the FDA clearly believes that its investigators have the right to take photographs during an inspection, there is no clear regulatory authority for the agency to do so.

Hillary Nicholas

Under Section 704 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 374, an FDA inspector has

the authority to enter and inspect "at reasonable times," "within reasonable limits," and in a "reasonable manner," any establishment in which food is manufactured, processed, packed, or held before or after introduction to interstate commerce.[3] As part of its investigation, an FDA inspector may inspect all "pertinent equipment," materials, containers and labeling, so long as the inspection is conducted in a "reasonable manner."[4] In addition, an FDA inspector may review records related to a company's food safety plan, and, in an emergency, general company records.[5] Ultimately, an FDA inspector is authorized to conduct a "careful, critical, official examination of a facility to determine its compliance with laws administered by FDA."[6] For all the authority it grants, however, Section 704 does not explicitly authorize or mandate the use of camera equipment during an inspection.

Despite the void of statutory authority, the FDA continues to instruct its inspectors to "not request permission from management to take photographs during an inspection" and to instead simply begin taking photos and video.[7] Should a company object to these tactics, inspectors are encouraged to "[a]dvise management the U.S. Courts have held that photographs may lawfully be taken as part of an inspection."[8] However, the two cases the FDA cites in support of this assertion — Dow Chemical Co. v. U.S. and U.S. v. Acri Wholesale Grocery Co. — do not stand for the unequivocal proposition suggested by the FDA.

In Dow Chemical Co. v. U.S.,[9] the U.S. Supreme Court considered the U.S. Environmental Protection Agency's authority to take undisclosed "aerial observation" photography of an industrial complex. While the court ultimately held that the use of aerial photography was within the EPA's statutory authority, extending that decision to other regulating bodies — let alone on-the-ground photography — is arguably quite a leap. Notably, even the FDA appears to recognize the limitations of the Dow Chemical decision, stating simply that "the court's language *seems* to address the right to take photographs by any regulatory agency."[10] Bottom line: This case has does not support the FDA's position that photography is a mandatory aspect of its investigational authority.

The second case cited by the FDA in support of its right to take photographs and video during an inspection is U.S. v. Acri Wholesale Grocery Co.[11] There, the U.S. District Court for the Southern District of Iowa considered whether it was reversible error to allow the introduction of photographs taken by FDA inspectors during warehouse inspections at trial. Importantly, based on the facts set forth in the opinion, while Acri Wholesale apparently did not give express permission for the FDA to take photographs, the company "fully consented" to the inspection and did not object when the inspectors began taking photographs.[12] The court ultimately determined that, "under the circumstances present" in that specific case, "the photographing of warehouse conditions by FDA agents was not unreasonable."[13] Moreover, the court found that the introduction of the photographs into evidence at trial was "merely cumulative of the inspectors' testimony regarding the insanitary conditions in the warehouse."[14] The court therefore concluded that the photographs were properly admitted in the later litigation.[15]

Like Dow Chemical, the Acri Wholesale decision has important limitations. To begin, the court did not determine (nor was it asked to determine) whether the FDA has an unfettered right to take photographs during an inspection. And the court was clear that its conclusion regarding the "reasonableness" of the FDA's actions was limited to the factual circumstances present in that specific case. At most, Acri Wholesale can be cited in support of the proposition that when a company does not affirmatively object to photography, and the photography is open and obvious during the FDA inspection, photographs taken during the inspection may be used as evidence in later litigation.

The FDA may cite these cases when challenged by a company during an inspection, but neither case

provides the agency with the support it claims. To date, no court has considered the broader issue of the FDA's right to take photographs during an inspection, nor has any court explicitly granted the FDA the authority to mandate the use of photography during an inspection and punish a company that fails to comply.

Recommendations

Whether the FDA has the authority to do so, warning letters like that sent to Homeolab make clear that the FDA's inspectors believe they are entitled to take photographs during an inspection. In addition, they have been trained to advocate for their right to use cameras during an inspection and will likely begin to take photos before a company even has a chance to address the issue on-site. Thus, what should a company do when it is faced with an FDA inspector and a camera? It is imperative that the company consider its approach to this question before the inspection begins, and, equally important, have a representative ready to firmly voice the company's decision when the FDA's inspector arrives.

One approach is to allow the inspector to take photographs. As the old adage goes, pick your battles. Photography during an FDA inspection continues to be a hot-button issue, and if a company is not concerned with the FDA photographing the premises, why push this issue? At a minimum, however, the company should appoint a representative to accompany the FDA's inspector and take corresponding photographs. This will provide the company with its own record of the inspection, and possibly generate additional context if it becomes necessary. For example, if the representative notices that the FDA's inspector is focusing on small details, the company's representative should take the same photo from different angles, or widen the shot to provide broader context. This will ensure that the company has its own complete record of the inspection that can serve as a counterpoint, should the FDA use the photos in future actions.

If after careful consideration, however, a company determines that it would like to enforce a "no-photo" policy during an inspection, it is well within its rights to do so. While the FDA will likely push back, there is no statutory authority that requires a food company to allow photography during an inspection. However, because this is such a contentious issue — and, more importantly, because a company certainly does not want to be viewed as impeding the inspection — it is essential that a company fully understand its rights and have a plan in place that addresses this issue before an inspection begins.

First and foremost, a company must be able to articulate a clear and reasonable rationale for its "no-photo" policy. If a company allows other visitors to photograph its plant and operations, then applying a different rule to an FDA inspector will not hold up under scrutiny. If a company is concerned about proprietary information, for example, then it should have an established, written "no-photo" policy in place well before an inspection takes place. This policy should extend to everyone — employees and visitors alike — and companies should be consistent in how this policy is applied and enforced. For example, a company claiming to have a strict "no-photo" policy should not also have a 360-degree virtual tour of its plant on the company's website. In addition to having a written policy in place, it is recommended that the company post "no-photo" signs throughout its facilities, placing the signs in locations visible to both employees and visitors.

Once an FDA inspector arrives, a designated company representative should direct the inspector to the company's "no-photo" policy before the inspection begins. As noted previously,the FDA instructs its inspectors to simply begin taking photographs without first asking for permission. As such, it is imperative to explain the company's photography policy in advance. Should a company fail to address this issue at the outset, it risks its silence being viewed as having consented to photography on the

premises.

The company's representative must also remember to remain calm. The FDA advises inspectors to strongly advocate for the use of camera equipment during an inspection, and the company should be prepared for an inspector to state that there is "clear" legal authority, threaten to call headquarters, or leave the site entirely. By understanding the confines of this supposed legal authority, the company's representative can firmly, but calmly, voice the company's objection to the use of camera equipment. If helpful, provide the inspector with reasons for not allowing cameras on the premises, including the proprietary nature of the manufacturing process, and the consequences of the unintentional release of confidential information.

Finally, if necessary, the company should direct the inspector to discuss the matter with corporate or outside legal counsel. Should the FDA seek an inspection warrant, legal counsel will need to be prepared to file a motion to quash or otherwise limit the information sought, and advocate reasonable limitations be placed on the inspector's photographs.

Conclusion

While there is no clear statutory or legal authority allowing for it, the FDA's investigators will likely attempt to take photos during an inspection, whether the company consents or not. Therefore, it is important for companies, and their counsel, to know a company's rights and establish a plan before the inspection begins. Companies who decide to enforce a "no-photo" policy during an FDA inspection are certainly well within their legal rights, but should be prepared to be labeled as "uncooperative" by the FDA.

To ease these tensions, preparation is key: Should a company determine it will not allow photography during an inspection, it is important that the company work closely with corporate and legal counsel to determine an approach that will protect the company's rights while remaining cooperative with the FDA so as to not impede the inspection.

M. Katie Gates Calderon and Lindsey K. Heinz are partners, and Hillary Nicholas is an associate at Shook Hardy & Bacon LLP in Kansas City, Missouri. They focus on regulatory compliance, enforcement and policy matters involving FDA- and U.S. Department of Agriculture-regulated products.

[1] See U.S. Food & Drug Admin., Warning Letter to Homeolab USA Inc. (Aug. 2, 2017), https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm570461.htm.

[2] Id.

[3] Fed. Food, Drug & Cosmetic Act, 21 U.S.C § 374(a)(1) (2012).

[4] Id.

[5] See id.

[6] See Fed. Food & Drug Admin, Investigations Operations Manual (IOM) (2017), section 5.1.2, at p. 229 (2017), https://www.fda.gov/ICECI/Inspections/.

[7] Id. at Section 5.3.4.1., at p. 259.

[8] Id.

[9] 476 U.S. 227 (1986).

[10] IOM (2017), section 5.3.4.1, at p. 259 (emphasis added).

[11] 409 F. Supp. 529 (S.D. Iowa 1976).

[12] See id. at 533.

[13] Id.

[14] Id.

[15] Id.
