

# FDA ON PREMISES: PHOTOGRAPHY AND THE PROTECTION OF TRADE SECRETS

by  
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Periodically, almost cyclically, practitioners in the food and drug bar receive waves of inquiries from persons being inspected by the Food and Drug Administration (FDA). The inquiries concern FDA investigators taking in-plant photographs. Can FDA take photographs? Can an inspected facility stop FDA? If not, how can an inspected establishment protect trade secrets?

FDA has long asserted that section 704 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. § 374, grants it the authority to take photographs in inspected establishments. Despite this assertion, the federal courts have never ruled on the narrow question of whether section 704 provides the agency that authority. The combination, however, of marginally supportive case law, decades of agency practice, the regulated industries' desire for "good relations" with FDA, the agency's ability to obtain an inspection warrant that invariably contains judicially approved authority to photograph, and the technological changes that have made photography and videography much more prevalent all make it unlikely that a court would rule today that FDA lacks statutory authority to take in-plant photographs.

If, however, a company has a good faith basis for asserting that visual depictions of particular portions of a facility would contain trade secrets, steps can be taken to protect that information. Prudence dictates that companies be proactive prior to and during an FDA inspection to ensure that the information is protected from disclosure to third parties. This LEGAL BACKGROUNDER will briefly describe the limits of FDA's authority and how companies may protect their trade secrets.

***Limits on FDA's Inspectional Authority.*** Under section 704 of the Act, FDA is authorized to enter establishments that manufacture, process, pack, or hold foods, drugs, medical devices, or cosmetics. FD&C Act § 704(a)(1)(A), 21 U.S.C. § 374(a)(1)(A). They are further authorized to inspect "at reasonable times and within reasonable limits and in a reasonable manner" the establishment and all "pertinent" equipment, finished and unfinished materials, containers, and labeling. FD&C Act § 704(a)(1)(B), 21 U.S.C. § 374(a)(1)(B).

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This statutory authority is constitutionally limited by the Fourth Amendment, which prohibits “unreasonable searches and seizures.” Judicial interpretation has shaped this prohibition such that industries “long subject to close supervision and inspection,” *Colonnade Catering Corp. v. United States*, 379 U.S. 72, 77 (1970), as well as “pervasively regulated business[es],” *United States v. Biswell*, 406 U.S. 311, 316 (1972), can be subjected to warrantless “searches” (read “inspections”). This is known as the *Colonnade-Biswell* exception to the warrant requirement. The debate over whether the *Colonnade-Biswell* exception applies to FDA-regulated entities was effectively ended for drug manufacturers in 1981 by the holding in *United States v. Jamieson-McKames Pharmaceuticals, Inc.*, 651 F.2d 532, 537 (8th Cir.). Similar holdings have been applied to the food industry by some district courts,<sup>1</sup> but FDA’s *Colonnade-Biswell* exception as applied to photography has not been actively litigated in the past two decades.

***FDA Assertion of Authority and Means of Obtaining Consent.*** Why have FDA-regulated industries given up? There are several practical and legal reasons why direct legal challenges to in-plant photography are not raised. First, many companies feel that they have nothing to hide and that their operations make quality products, so no potential harm is perceived. Second, FDA may deem a refusal to allow photography to be a refusal of inspection, which is a “prohibited act” (21 U.S.C. § 331(f)) subject to injunction (21 U.S.C. § 332(a)) and criminal prosecution as a misdemeanor.<sup>2</sup> While these sanctions are extreme, the mere threat of them can be persuasive.

FDA can also seek an Administrative Inspection Warrant from a United States District Court. While often in the past, FDA inspectors would not press the matter, if a warrant is sought by FDA, the authority to photograph will inevitably be part of the application<sup>3</sup> and very likely granted by the court. Internal FDA materials directly address photography and administrative inspection warrants:

Inspection warrants may be sought when inspection has been refused completely or when refusals have been encountered in limited areas; *for example, when photography or sample collection has been refused. . . .* Also, FDA may seek a preemptive inspection warrant prior to initiating a scheduled inspection when there is a documented corporate policy mandating refusal in a particular area (such as photography, sample collection, or copying of records) . . . .<sup>4</sup>

The FDA Investigations Operations Manual (IOM) treats in-plant photography as a *fait accompli*:

Do not request permission from management to take photographs during an inspection. Take your camera into the firm and use it as necessary just as you use other inspectional equipment. If management objects to taking photographs, explain that photos are an integral part of an inspection and present an accurate picture of plant conditions. Advise management the U.S. Courts have held that photographs may lawfully be taken as part of an inspection.<sup>5</sup>

The most recent edition of the IOM highlights FDA’s renewed emphasis on its asserted authority to photograph within inspected facilities. “The ‘In-Plant Photographs’ section in Chapter 5 has been revised to specify actions *required* by the investigator and district management when a firm refuses photography during an inspection.<sup>6</sup> The 2012 revision reveals that FDA is obviously weary of arguing over whether it can take in-plant photographs:

If management refuses, obtain name and contact information for the firm’s legal counsel, and advise your district management immediately. If the firm does not have legal counsel on retainer, collect the name and contact information for the most responsible individual. District management will inform their ORA Regional Counselor in the Office of Chief Counsel (OCC) of the situation, and OCC will then

contact the firm's legal counsel or most responsible individual to discuss FDA's legal right to take pictures during inspections. . . . If you have already taken some photos do not surrender film to management. . . . See IOM 5.3.4.5.<sup>7</sup>

Still, doubts remain within regulated industries whether FDA is acting within its statutory authority. The two cases cited on the laminated card carried by FDA investigators, *Dow Chemical v. United States*, 476 U.S. 227 (1986), and *United States v. Acri Wholesale Grocery Company*, 409 F. Supp. 529 (S.D. Iowa 1976), do not stand for the proposition that FD&C section 704 authorizes in-plant photography during inspections. *Dow Chemical* involved aerial photography by the Environmental Protection Agency – photographs taken from a different and public place by a different agency pursuant to a different statutory scheme. *Acri Wholesale Grocery* was a criminal case in which the court held that photographs taken inside a plant during inspection were admissible when the company failed to object at the time of inspection. While there is broad dicta in the court's opinion about FDA's authority to take photographs during plant inspections, legal commentators regularly dismiss the case as not directly supporting FDA's assertion of authority, not addressing the important question of whether an inspected facility may refuse to permit in-plant photography, and not discussing the important question of the consequences of such a refusal.<sup>8</sup>

Ultimately, were a direct challenge to FDA's assertion of authority under FD&C Act section 704 for in-plant photographs mounted, the court would look to the reasonableness standard articulated in the statute, *i.e.*, inspection is authorized during "reasonable times," "within reasonable limits," and in a "reasonable manner." Are photographs unreasonable?

Regulated industries should consider how ubiquitous photography and video surveillance have become in this century. The vast majority of the millions of mobile telephones in this country have cameras. Major news organizations have come to rely on photographs and videos taken by persons outside of their organizations. Governments, businesses, and some private citizens watch public and private spaces with photographic and video surveillance equipment. The internet brings both the extraordinary and the banal to our computers and mobile devices. Photographs and videos are our constant companions.

Certainly photographs of insanitary conditions can be off-putting, but that should not be a sufficient basis to characterize photography as an "unreasonable" means of inspection. In an enforcement action, FDA would certainly attempt to offer photographs into evidence, but, absent at least an objection to the photography made at the time of the inspection, a motion to suppress the photographs would be difficult to win. *Cf. Acri Wholesale Grocery, supra* at 534 (once the "validity" of the inspection was established, the "propriety" of a photographic "search" is coextensive with the validity of the inspection and defendants had consented to inspection). If the inspected establishment's concern is that photography unfairly portrays conditions at the facility, in a jury trial,<sup>9</sup> defendants could still move to exclude photographs under Fed. R. Evid. 403.<sup>10</sup>

While regulated industries may have a tough time stopping FDA from taking photographs or videos and using those materials in enforcement proceedings, companies can take steps to protect against unfair characterization of their plant and operations. Companies should take their own photos at the same time FDA takes theirs. A company's own photographs may look better and be able to counter the evidentiary value of FDA's.

***Protection of Trade Secrets.*** If a company has real concerns about proprietary information being disclosed by photographs or videos, it should take the following steps:

- Have a written policy regarding the photography/videography ban in place prior to inspection, with an assertion that the reason for the policy is to protect trade secret/business confidential information.
- Post "NO PHOTOGRAPHY OR VIDEOGRAPHY" signs in the appropriate areas.

- Provide FDA with the written policy at the start of the inspection.
- Notify FDA in writing at the time of the inspection close-out or shortly thereafter that the company asserts that the photographs contain trade secret/business confidential information the disclosure of which would cause competitive harm to the company.

This LEGAL BACKGROUNDER has previously noted that a policy forbidding in-plant photographs may garner an Administrative Inspection Warrant. For that reason, the company should carefully explain to FDA investigators that it does not intend to refuse inspection,<sup>11</sup> but rather that the photography/videography ban is to protect trade secrets. In designating areas that are off-limits, the company should be prepared to explain if any of the company's own surveillance equipment captures the area and how the company protects the confidential nature of that surveillance. The respectful presentation of a well-founded policy may result in an inspector exercising greater discretion in taking photographs.

While none of this will stop FDA from using the photographs or videos in an injunction or seizure action, or criminal prosecution, it would put FDA on notice that the material should not be disclosed under the Freedom of Information Act (FOIA). 5 U.S.C. § 552(b)(4); 21 C.F.R. § 20.61. A company should also request in writing copies of the photographs. A copy of the Establishment Inspection Report (EIR: FDA's narrative of the inspection, with exhibits) should be routinely provided to the company once the agency concludes that the inspection is closed. FDA, "[Procedure for Release of Establishment Inspection Report](#)." FDA will consider the EIR exempt from disclosure as long as the case file remains open.<sup>12</sup>

It is very likely that the day has arrived in which in-plant photographs during FDA inspections are no longer worth fighting about. What remains, however, is the prudent practice of protecting proprietary information. A well-founded, written policy regarding photography and videography should be considered an important part of protecting a firm's assets.

<sup>1</sup> *United States v. New England Grocers Supply Co.*, 488 F. Supp. 230 (D. Mass. 1980); *United States v. Gel Spice Co.*, 601 F. Supp. 1214 (E.D.N.Y. 1985).

<sup>2</sup> FD&C Act § 303; 21 U.S.C. § 333(a)(1). The offense is also punishable as a three-year felony upon a prior conviction for another FD&C Act conviction, or if the refusal to permit inspection is committed with the intent to defraud or deceive.

<sup>3</sup> FOOD AND DRUG ADMIN., [REGULATORY PROCEDURES MANUAL](#) (2011) at § 6-3-2-1.b.ii [hereinafter RPM].

<sup>4</sup> RPM (2011) at § 6-3-2 (emphasis supplied).

<sup>5</sup> IOM § 5.3.4.1.

<sup>6</sup> IOM Foreword 2012 (emphasis supplied).

<sup>7</sup> IOM § 5.3.4.1.

<sup>8</sup> E.g., Branding and Ellis, *Underdeveloped: FDA's Authority to Take Photographs During an FDA Establishment Inspection Under Section 704*, 58 FOOD & DRUG L.J. 9, 13-14 (2003) [Since the publication of this article, one of its authors, Frederick H. Branding, has become a Principal with OFW Law, as are the authors.].

<sup>9</sup> A jury trial would be used in a criminal prosecution under the FD&C Act, and can be demanded in a seizure action. FD&C Act § 304(b); 21 U.S.C. § 334(b). If an injunction action is joined with a seizure action, a jury trial made be had upon demand on questions of fact. *United States v. 5,906 Boxes (Alcon Laboratories)*, 745 F.2d 105 (1<sup>st</sup> Cir. 1984).

<sup>10</sup> "The court may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Successful Rule 403 objections are exceedingly rare in bench trials.

<sup>11</sup> If, during any FDA inspection, an FDA investigator suggests or states that they consider the company to be "refusing" inspection, counsel should be immediately contacted.

<sup>12</sup> 5 U.S.C. § 552(b)(7); 21 C.F.R. § 20.64 (law enforcement exception to FOIA)