



Photo Shop

Facility photographs and FDA inspection authority

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WITH RESPECT TO FACTORY INSPECTIONS, section 704 of the Federal Food, Drug, and Cosmetic Act ("FDCA") generally allows that for the purposes of enforcing the FDCA, appropriate officials of the U.S. Food and Drug Administration ("FDA"), after presenting appropriate credentials and with written notice, may enter (at reasonable times) any place in which regulated products are manufactured, processed, packed, or held and to reasonably inspect such place. This section of the FDCA explicitly addresses FDA's authority to conduct inspections: this inspection authority is well established in some areas (e.g., inspections of physical facilities), but remains questionable in others. In particular, the language of section 704 does not expressly state that FDA is authorized to take photographs during in-plant inspections. Despite the lack of specific authority, it is not uncommon for an inspector to attempt to utilize a camera during an inspection. As a consequence, any company developing or manufacturing regulated products should be prepared to address this specific issue.

Unbeknownst to most companies inspected by FDA, the agency trains its inspectors via its Investigations Operation Manual to take a camera into facility inspections and to use the device during the course of an investigation *without* asking the company's permission. Specifically, with respect to in-plant photography, the most recent version of the Investigations Operation Manual provides:

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.

If management continues to refuse, provide them with the following references:

Dow Chemical v. United States, 476 U.S. 227 (1986). This Supreme Court Decision dealt with aerial photographs by EPA, but the Court's language seems to address the right to take photographs by any regulatory agency. The decision reads in part, "**** When Congress invests an agency with enforcement and investigatory authority, it is not necessary to identify explicitly each and every technique that may be used in the course of executing the statutory mission. ****"

United States of America v. Acri Wholesale Grocery Company, A Corporation, and JOSEPH D. ACRI and

ANTHONY ACRI, Individuals, U.S. District Court for Southern District of Iowa. 409 F. Supp. 529. Decided February 24, 1976.

If management refuses, advise your supervisor so legal remedies may be sought to allow you to take photographs, if appropriate. If you have already taken some photos do not surrender film to management. Advise the firm it can obtain copies of the photos under the Freedom of Information Act.

As this section of the Investigations Operations Manual indicates, FDA inspectors are directed not to "request permission from management to take photographs during an inspection." This direction suggests that an inspector should simply attempt to take pictures of the facility, without prior announcement or request. Only after management objects to these photographs are inspectors to "[a]dvice management the U.S. Courts have held that photographs may lawfully be taken as part of an inspection" and cite two specific cases if necessary, i.e. *Dow Chemical v. United States* and *United States of America v. Acri Wholesale Grocery Company, A Corporation, and JOSEPH D. ACRI and ANTHONY ACRI*.

Because of the emphasis FDA inspectors are directed to place on these two cases, some basic information about these cases should be considered:

- In *Dow Chemical*, Dow was operating a 2,000-acre facility manufacturing chemicals in Midland, MI. Because of intentionally tight security, there was no public view of the facility from the ground. The Environmental Protection Agency ("EPA"), pursuant to the Clean Air Act, requested an on-site inspection of the plant, which Dow in turn refused. The EPA then hired a commercial aerial photographer to take photos of the facility within lawful navigable airspace without a warrant. Dow brought suit for violations of the Fourth Amendment, and claimed that the aerial photography was beyond the scope of statutory investigative authority under the Clean Air Act. In this case, the Court determined the aerial photography was within the EPA's statutory authority, because, "[w]hen Congress invests an agency with enforcement and investigatory authority, it is not necessary to identify explicitly each and every technique." In addition, the Court determined that the taking of photography from navigable airspace was not a violation of the Fourth Amendment.

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- In *Acri Wholesale*, FDA conducted a warrantless inspection of the Acri Wholesale Grocery Company warehouse in Des Moines, IA, in 1973. A massive rodent infestation was found, and photographs were taken of these violations. In the following criminal prosecution, Acri unsuccessfully moved to suppress the warehouse photos. Acri appealed the trial court judgment claiming the photos were taken outside the scope of the FDCA as they were taken without Acri's explicit permission, even though no objection had been made at the time of the inspection. The court found that 1) because a "flexible standard of 'reasonableness' defines the contours of an FDA inspection," 2) because photography of warehouse conditions in this circumstance was not unreasonable as the agents were in the warehouse pursuant to lawful authority and following all procedural requirements, and 3) because the defendants consented to the inspection and did not object to the obvious photography, the trial court's admission of the photos was upheld.

As seen by the general summary of these cases, neither provides direct support for FDA's assertion of authority to obtain in-facility photographs. Indeed, both the inspections conducted in *Acri* and *Dow* proceeded on the basis of implied consent. The decisions suggest that if *no* company representative objects to the use of the camera or if the method of observation is rea-

sonably available to the general public (e.g., a tour of the facility open to the public allows photography), it is reasonable for the inspectors to photograph the facility.

Given the lack of specific statutory language and definitive case law authorizing photography during an FDA inspection, it is essential that firms involved in the development and manufacture of regulated products address the issue of handling inspection photographs in a written policy. The company should consider its position on in-facility photographs and decide whether it will permit FDA inspectors to take photographs inside its facilities. If the company decides to permit photography, it should also consider if there are any exceptions to the general permission, e.g., for areas of the facility containing certain proprietary machinery. The company should include the photography allocation and any associated limitations in their inspection policy, along with the underlying justification for the policy.

In the alternative, should a company determine it will not permit photography, the photography prohibition should be specified within internal policies. After determining and articulating its policy on the matter, companies should also provide comprehensive training on the issue. Moreover, the company should consider posting notices of the limitation, including stating that photography inside of the facility is specifically prohibited, and any inspector who brings a camera should be asked to leave it outside the facility.

The issue of in-facility photography should be addressed with the FDA prior to the start of the inspection. Although FDA inspectors are not required to partake in a pre-inspection conference, most inspectors will participate in such a conference if requested. A company employee trained to manage inspections should meet with the inspector to gain an understanding of why the inspection is being conducted and the likely scope of the inspection. While the trained employee should cover a number of other issues during the pre-inspection conference, he or she should inform the inspector of any company policies regarding the use of cameras during the inspection. For example, if the company prohibits photography inside the facility, the company's policy regarding photography should be explained during the pre-inspection conference, and an inspector carrying a camera should be asked to leave the apparatus outside.

Finally, if an inspector does take photographs of the facility, regardless of whether the photography is contrary to the company's expressed policy, the company should be aware that it can obtain copies of all photographs taken during the investigation. Again, according to the Investigations Operations Manual, inspectors are trained, "[d]o not routinely advise firms they may have copies of photos. However, if management of the firm initiates the request, advise them it is possible to obtain copies of photographs taken in their plant under the Freedom of Information Act. . . . Since photographs are records in an investigative file, they are not available under the Freedom of Information Act until the file is closed."

For companies inspected by FDA, time devoted to developing and communicating a policy regarding the use of in-facility photographs is well-spent. Companies that have considered the issue prior to the arrival of an inspector are better positioned to handle the investigator armed with a camera. ■

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