



## Don't Come Around Here No More: A Drug Company Receives a Warning Letter for Limiting Inspection

Alan G. Minsk

In the “what were they thinking department,” a drug company located outside of the United States recently received a Warning Letter for limiting and refusing an FDA inspection.<sup>1</sup> In addition, the agency placed the company on an Import Alert, not allowing the company’s products to be imported into the United States. Tom Petty and the Heartbreakers’ 1985 hit, “Don’t Come Around Here No More,” and the weird Alison in Wonderland video come to mind.

According to the Warning Letter, the company barred access to the quality control laboratory, directing “employees to stand shoulder-to-shoulder, barring our investigator from accessing portions of the laboratory and the equipment used to analyze drugs for U.S. distribution.” The company also refused to provide copies of complaint records. Finally, the investigator tried to take pictures of a piece of equipment used to manufacture the drugs, but the company official “impeded the inspection by preventing our investigator from photographing this piece of equipment.”

### AGG Observations

- A company should have procedures to handle inspections and not allow an investigator to roam unattended. However, FDA is allowed to review and copy those records concerning product manufacture, distribution, and handling.<sup>2</sup> There are limits to FDA’s reach, such as access to pricing data but, in general, if the inspection or inquiry relates to quality-related concerns, FDA is entitled to access and will have the better argument if its inspection authority is challenged.
- Barring or impeding an FDA inspection of areas where the agency is allowed to inspect is a prohibited act.<sup>3</sup>
- The issue of FDA taking photographs is more tricky. FDA believes it is allowed to take photographs, citing two court cases, but in our opinion neither one is directly on point.<sup>4</sup> We recommend that companies make clear the reason photocopying in the plant is not allowed in the company’s standard operating procedures. In addition, firms should publicize and post a “no photos” policy at a facility. While an FDA investigator can disagree and insist, the investigator will frequently relent or at worst, ask for the name of the attorney who represents the company so that a follow-up discussion can occur. We cannot tell from the Warning Letter referenced above whether the company had such a policy or whether the investigator ignored a request not to photograph.
- For companies or sites outside of the United States, there is no express statutory provision that permits FDA to inspect. However, the agency can detain or issue an Import Alert if it believes that an imported product “appears” to be unlawful.<sup>5</sup> Thus, if FDA cannot inspect a facility to ensure compliance, it can tell a company that it does not have adequate assurances that the imported product is acceptable and, in an abundance of caution, detain the

1 [www.fda.gov/ICECI/EnforcementActions/WarningLetters/2016/ucm522801.htm](http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2016/ucm522801.htm) (last accessed October 15, 2016.)

2 21 U.S.C. § 374.

3 21 U.S.C. § 331(e) and (f).

4 See *Dow Chemical v. United States*, 476 U.S. 227 (1986); *United States v. Acri Wholesale Grocery Company*, 409 F. Supp. 529 (S.D. Iowa 1976); see also Investigations Operations Manual 5.3.4.1.

5 21 U.S.C. § 381(a).

product. So, an ex-U.S. company normally allows the FDA inspection.

- It is important that companies know their rights during an inspection and be trained accordingly. A firm is not required to give an investigator the keys to the facility and then leave the investigator with unfettered access. However, FDA has statutory authority to inspect facilities and review records, with limitations. Each company must balance the benefits and risks of restricting FDA access versus being cooperative. If a company decides it does not want (or is not required) to provide an FDA investigator with certain information, it must be confident it is right on the law and consider alternatives to satisfying FDA's request. An uncooperative company will often find itself the subject of a larger inspection, a Warning Letter, or both. On the other hand, an overly cooperative company that does not know FDA's inspectional boundaries might be unduly harming itself through voluntary disclosure of information that FDA by law is not entitled to receive or review.
- Procedures, training and a knowledge of the law are essential. But telling FDA "don't come around here no more" is ill-advised.

## Authors and Contributors

---

**Alan G. Minsk**

Partner, Atlanta Office  
404.873.8690  
alan.minsk@agg.com

not *if*, but *how*.<sup>®</sup>

## About Arnall Golden Gregory LLP

---

Arnall Golden Gregory, a law firm with more than 150 attorneys in Atlanta and Washington, DC, employs a “business sensibility” approach, developing a deep understanding of each client’s industry and situation in order to find a customized, cost-sensitive solution, and then continuing to help them stay one step ahead. Selected for The National Law Journal’s prestigious 2013 Midsize Hot List, the firm offers corporate, litigation and regulatory services for numerous industries, including healthcare, life sciences, global logistics and transportation, real estate, food distribution, financial services, franchising, consumer products and services, information services, energy and manufacturing. AGG subscribes to the belief “not if, but how.” Visit [www.agg.com](http://www.agg.com).

**Atlanta Office**

171 17th Street, NW  
Suite 2100  
Atlanta, GA 30363

**Washington, DC Office**

1775 Pennsylvania Avenue, NW  
Suite 1000  
Washington, DC 20006

To subscribe to future alerts, insights and newsletters: <http://www.agg.com/subscribe/>

©2016. Arnall Golden Gregory LLP. This legal insight provides a general summary of recent legal developments. It is not intended to be, and should not be relied upon as, legal advice. Under professional rules, this communication may be considered advertising material.