Administrative Inspections by the Food and Drug Administration: The Role of the Department of Justice

JOHN R. FLEDER, ESQ.*

I. INTRODUCTION

Both Congress and the courts have long recognized the importance of protecting the public through enforcement of the Federal Food, Drug, and Cosmetic Act.[1] One essential vehicle through which the Food and Drug Administration (FDA) fulfills its statutory mandate to protect the public health and safety is through administrative inspections. Inspections provide the statutory means by which the FDA gathers information and facts necessary to determine whether an actionable violation of the Act has occurred.[2] Indeed, the "FDA's primary statutory tool to ensure compliance with the Act is the statutory inspection authority granted in 21 U.S.C. § 374."[3]

Clearly, the industries the FDA regulates accept its statutory role in protecting the public health and safety through administrative inspections. Of the more than 20,000 inspections conducted by the FDA in fiscal year 1988,[4] the agency asked the Department of Justice to obtain court-issued inspection warrants in only twelve cases. Thus, the Department of Justice plays no role in most of the inspections conducted by the FDA.

A. *Congress has Conferred Broad Inspection Powers*

To enforce the Act, section 374(a)(1) of title 21 of the *United States Code* provides that duly designated FDA officials

> upon presenting appropriate credentials and a written notice to the owner . . . are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or

---

* Mr. Fleder is Director, Office of Consumer Litigation, Civil Division, United States Department of Justice. A previous version of this paper was presented at The Food and Drug Law Institute's Inspections Workshop, Buffalo, NY (June 10, 1986). The views expressed in this article are Mr. Fleder's and not necessarily the views of the Department of Justice.

Heidi A. Garland, a trial attorney in the Office of Consumer Litigation, contributed to this article.

1. Pub. L. No. 75-717, 52 Stat. 1040 (1938), as amended 21 U.S.C. §§ 301-392 (1982).
2. Southeast Minerals v. Harris, 622 F.2d 758, 765 (5th Cir. 1980).
3. United States v. Gel Spice Co., Inc., 773 F.2d 427, 429 (2d Cir. 1985), *cert. denied*, 474 U.S. 1060 (1986). The FDA also has inspectional powers under the Federal Import Milk Act, Pub. L. No. 69-625, 44 Stat. 1102 (1927) (codified at 21 U.S.C. § 143), and four provisions of the Public Health Service Act, ch. 373, §§ 351(c), 353, 360A, 361(a), 58 Stat. 702 (1944), 102 Stat. 2903 (1988), 82 Stat. 1182 (1968), 58 Stat. 703 (1944) (codified at 42 U.S.C. §§ 262(c), 263a(g), 263(i), and 264(a) (1982 and Supp. 1989)).
4. The FDA's Program Oriented Data System for fiscal year 1988.

> cosmetics are manufactured, processed, packed, or held . . . ; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein.

This statutory grant confers broad inspection powers. While Congress did specify what is subject to inspection ("all pertinent equipment, finished and unfinished materials, containers, and labeling . . ."), it did not restrict the manner of inspection. Rather, it provided for any manner of inspection that is reasonable.

Congress refused to hamstring the FDA with a specific list of permissible inspection techniques. What constitutes a reasonable inspection depends on the circumstances of each case. Nevertheless, Congress recognized that "inspection means to 'examine critically' and the words of the statute should be given meaning consistent with the overall purpose of the act in protecting the public."[5] Accordingly, Congress intended this grant of authority to encompass all investigative tools that reasonably accomplish the purpose of the inspection.

B. *The FDA Can Conduct Warrantless Inspections*

Recognizing the vital public health considerations involved in enforcing the Act, Congress and the courts have refused to limit the FDA's inspection authority by imposing court-issued warrant requirements such as those applicable to many other agencies. The bases for such judicial forbearance are rooted in the history of pervasive regulation that characterizes the industries that are subject to FDA inspection. The food industry has been closely regulated by the FDA since 1906. Thus, the FDA may conduct nonconsensual administrative inspections under section 374 without either a criminal search warrant or an inspection warrant.[6] Similarly,

---

5. S. REP. NO. 712, 83d Cong., 1st Sess. 4 (1953).

6. United States v. New England Grocers Supply Co., 488 F. Supp. 230, 237-38 (D. Mass. 1980); United States v. Acri Wholesale Grocery Co., 409 F. Supp. 529, 533 (S.D. Iowa 1976); United States v. Business Builders, Inc., 354 F. Supp. 141, 143 (N.D. Okla. 1973); United States v. Del Campo Baking Mfg. Co., 345 F. Supp. 1371, 1376 (D. Del. 1972); R.J. French Co. v. FDA, Food Drug Cosm. L. Rep. (CCH) ¶ 38,258 (D. Idaho 1984); United States v. Paul's Bakery, Inc., Crim. No. 70-14-180 (S.D. Tex. 1972); and United States v. Iwen, No. 77-Cr-47 (E.D. Wisc. 1977). *Compare* United States v. Roux Laboratories, Inc., 456 F. Supp. 973, 977 (M.D. Fla. 1978) stating, in *dicta*, that a valid warrant must be obtained by the FDA absent consent or emergency circumstances.

In United States v. Thriftimart, Inc., 429 F.2d 1006, 1009 (9th Cir.), *cert. denied*, 400 U.S. 926 (1970), the court noted: "The citizen [in FDA inspections] is not likely to be uninformed or surprised. Food inspections occur with regularity . . . . The inspection itself is inevitable." *Thriftimart* also concluded that the FDA need not give the firm to be inspected advance notice of an inspection. *Id.* at 1010. Similarly, advance notice of an inspection need not be given by a government agency (even pursuant to a warrant) where surprise is not necessary to accomplish the purposes of the inspection. Bunker Hill Co., Inc. v. EPA, 658 F.2d 1280, 1285 (9th Cir. 1981).

Generally, warrantless searches are considered "unreasonable" under the fourth amendment; commercial premises as well as homes fall under the fourth amendment's protection. *See, e.g.*, Marshall v. Barlow's, Inc., 436 U.S. 307, 312 (1978) (inspection under Occupational Safety and Health Act of

the drug and medical device industries, which historically also have been closely regulated, are subject to warrantless FDA inspections under this statutory provision.[7]

The legislative history of the FDA's inspectional authority demonstrates that Congress considered, and rejected, suggestions that the FDA be permitted to inspect only with the consent of the firm to be inspected or with a judicially-issued warrant.[8] In 1953, Congress amended section 374 as a result of a 1952 United States Supreme Court decision invalidating this provision.[9] After careful consideration, the House concluded that warrantless and compelled inspections by the FDA were appropriate and that such inspections would not violate the fourth amendment.[10]

Indeed, failure to allow an inspection subjects the person and firm the FDA is seeking to inspect to criminal penalties under the Act.[11] In Febru-

---

1970, Pub. L. No. 91-596, § 8, 84 Stat. 1598 (codified at 29 U.S.C. § 657(a) (1982)). However, inspections of industries historically regulated by close supervision and inspection, Colonnade Catering Corp. v. United States, 397 U.S. 72, 77 (1970) (liquor), and businesses pervasively regulated, United States v. Biswell, 406 U.S. 311, 316-17 (1972) (firearms), may be conducted without a warrant. But see United States v. Kramer Grocery Co., 418 F.2d 987 (8th Cir. 1969) and United States v. Stanack Sales Co., 387 F.2d 849 (3d Cir. 1968), two pre-*Biswell/Colonnade* cases that stated that consent of management is ordinarily required for inspectors of the FDA to conduct a warrantless inspection.

The *Biswell/Colonnade* exception to the warrant requirement was reaffirmed in Donovan v. Dewey, 452 U.S. 594 (1981):

> [A] warrant may not be constitutionally required when Congress has reasonably determined that warrantless searches are necessary to further a regulatory scheme and the federal regulatory presence is sufficiently comprehensive and defined that the owner of commercial property cannot help but be aware that his property will be subject to periodic inspections undertaken for specific purposes.

Id. at 600. *Dewey* held valid a provision of the Federal Coal Mine Safety and Health Act, Pub. L. No. 91-173, title I, § 103, 83 Stat. 749 (1969) (codified at 30 U.S.C. § 813(a) (1982)), that authorizes warrantless inspections.

In Dow Chemical Co. v. United States, 476 U.S. 227, 237-38 (1986), the Court, citing *Dewey*, noted "that the Government has 'greater latitude to conduct warrantless inspections of commercial property' because 'the expectation of privacy that the owner of commercial property enjoys in such property differs significantly from the sanctity accorded an individual's home.' "

Recently, in New York v. Burger, 482 U.S. 691, 700 (1987), the Court held that police officers could conduct a warrantless search of an automobile junkyard pursuant to a New York statute, stating:

> [a]n expectation of privacy in commercial premises, however, is different from, and indeed less than, a similar expectation in an individual's home. . . . This expectation is particularly attenuated in commercial property employed in "closely regulated" industries . . . . "Certain industries have such a history of government oversight that no reasonable expectation of privacy . . . could exist for a proprietor over the stock of such an enterprise." (citations omitted)

7. United States v. Jamieson-McKames Pharmaceuticals, Inc., 651 F.2d 532, 537-39 (8th Cir. 1981) ("virtually every phase of the drug industry is heavily regulated"), *cert. denied*, 455 U.S. 1016 (1982) (cited with approval in Illinois v. Krull, 480 U.S. 340, 351 (1987)); United States v. Acklen, 690 F.2d 70, 75 (6th Cir. 1982); United States v. Schiffman, 572 F.2d 1137, 1142 (5th Cir. 1978); United States ex rel. Terraciano v. Montanye, 493 F.2d 682, 684-85 (2d Cir.), *cert. denied*, 419 U.S. 875 (1974); United States v. Torigian Laboratories, Inc., 577 F. Supp. 1514, 1520 (E.D.N.Y.), *aff'd mem.*, 751 F.2d 373 (2d Cir. 1984). *But see* United States v. I.D. Russell Laboratories, 439 F. Supp. 711 (W.D. Mo. 1977).

8. H.R. REP. No. 708, 83d Cong., 1st Sess. (1953).

9. United States v. Cardiff, 344 U.S. 174 (1952).

10. *See* H.R. REP. No. 708, 83d Cong., 1st Sess. (1953).

11. Pub. L. No. 75-717, §§ 301(f), 303, 52 Stat. 1042, 1043-44, as amended 21 U.S.C. §§ 331(f), 333. United States v. Iwen, No. 77-Cr-47 (E.D. Wisc. 1977); United States v. Litvin, 353 F.

ary 1986, a pharmaceutical firm and two of its officers entered guilty pleas to felony charges under these provisions.[12]

C. *The FDA's Inspectional Authority Encompasses All Enforcement Tools*

It is also clear that the FDA may permissibly employ its inspectional authority under section 374 whether the agency is considering a civil seizure action,[13] an injunction suit to restrain violations of the Act,[14] or even possible criminal charges.[15] In sum, the agency's enforcement intentions (if any) are simply not pertinent to the FDA's authority to conduct an inspection under section 374.[16]

D. *Situations Necessitating a Warrant*

Although the FDA is under no obligation to seek a court-issued administrative inspection warrant, practical considerations may require application to a court for such a warrant if, after refusal by the firm to be inspected or in anticipation of such a refusal, inspections are to be carried out in a timely and effective fashion.[17] The possibility of criminal sanc-

---

Supp. 1333, 1338 (D.D.C. 1973); United States v. Del Campo Baking Mfg. Co., 345 F. Supp. at 1376; and United States v. Cruez, 144 F. Supp. 229, 235 (E.D. Ill. 1956).

12. United States v. Lewis Michael Orlove, Gary R. Dubin and Generix Drug Corp., No. 85-6007-CR (Paine) (S.D. Fla. Feb. 1986).

13. Pub. L. No. 75-717, § 304, 52 Stat. at 1044-45, as amended 21 U.S.C. § 334.

14. *Id.* § 302, 52 Stat. at 1043, as amended 21 U.S.C. § 332. In In re Stanley Plating Co., Inc., 637 F. Supp. 71 (D. Conn. 1986), the court rejected the company's argument that once the Environmental Protection Agency (EPA) had initiated an enforcement suit, it could only inspect the firm pursuant to the *Federal Rules of Civil Procedure*. Accordingly, the court denied a motion to quash an inspection warrant issued pursuant to 42 U.S.C. § 6927(a).

15. Pub. L. No. 75-717, § 303, 52 Stat. at 1043-44, as amended 21 U.S.C. § 333.

16. United States v. Gel Spice Co., Inc., 773 F.2d at 432; United States v. Jamieson-McKames, 651 F.2d at 541-42. *Accord* United States v. Nechy, 827 F.2d 1161 (7th Cir. 1987) (and the cases cited therein), involving a Drug Enforcement Administration (DEA) inspection of a pharmacy. See also New York v. Burger, 482 U.S. at 712-18, where the Court stated that a warrantless administrative search conducted pursuant to the New York statute was not unconstitutional "simply because, in the course of enforcing it, an inspecting officer may discover evidence of crimes. . . ." But see Turner v. Dammon, 848 F.2d 440 (4th Cir. 1988) where the court concluded that execution of Maryland's "bar check program" raised serious constitutional issues because of the frequency of (over one hundred) searches of one bar.

17. There are situations where a warrant is not needed. One such situation is informal resolution by consent of the inspected firm through a telephone call, or visit by a government attorney or FDA official. *See, e.g.*, United States v. Thriftimart, Inc., 429 F.2d at 1010; United States v. Hammond Milling Co., 413 F.2d 608, 611 (5th Cir. 1969), *cert. denied*, 396 U.S. 1002 (1970); and United States v. Jacobs, Food Drug Cosm. L. Rep. (CCH) ¶ 38,123 (E.D. Cal. 1989) (court held that defendant had "consented" to inspection of his animal hospital's records when he did not object to the FDA, even though the notice of inspection issued by the inspector failed to indicate that the records the FDA sought to inspect were not subject to the agency's inspectional authority). A warrant is also not required in emergency situations. Camera v. Municipal Court, 387 U.S. 523, 539 (1967). In establishing this principle, the Court cited North Am. Cold Storage Co. v. City of Chicago, 211 U.S. 306 (1908), permitting the urgent necessity of seizing unwholesome food without a warrant. There is also no question that the FDA can inspect if the inspector is in a place that he or she has a statutory right to be, and the property is within plain view. *See* Air Pollution Variance Bd. v. Western Alfalfa Corp., 416 U.S. 861 (1974); Marshall v. Barlow's, Inc., 436 U.S. at 315. In Dow Chemical

tions for refusing to permit an inspection may encourage, but will not ensure, immediate access to the establishment sought to be inspected. In order to enable the FDA to carry out its statutory right to conduct lawful inspections without interference, the Department of Justice actively assists in the process of obtaining and executing inspection warrants.[18]

II. The FDA's Referral of Applications for Inspection Warrants

The FDA, through the Director of its Office of Enforcement and with the approval of its Chief Counsel, refers proposed inspection warrants to the Office of Consumer Litigation (OCL) of the Civil Division, United States Department of Justice.[19] A referral generally includes a background memorandum, a copy of the proposed inspection warrant application, and the proposed warrant. The FDA referral normally contains a brief account of the agency's prior inspection efforts, including, for example, whether inspection was refused altogether, whether inspections were allowed only in limited areas, and whether the taking of photographs and/or the collection of samples was refused. The OCL coordinates the application process with the FDA and the appropriate United States Attorney's office. Generally, the OCL completes its review within forty-eight hours. In emergency situations, the OCL has authorized filing a warrant application within a few hours of receipt of the FDA's referral.

III. Review by the Office of Consumer Litigation

In reviewing the FDA's application for an inspection warrant, the OCL generally considers a number of factors prior to approving the matter and contacting the appropriate United States Attorney's office. The OCL attorney's initial responsibilities are to ensure that the inspection falls within the mandates of section 374, or another law enforced by the FDA, and that the facts, as stated in the application, justify seeking a

---

Co. v. United States, 476 U.S. at 234-39, the Supreme Court further broadened the "open fields" doctrine (pertaining to areas observable by the public in which an individual may not legitimately demand privacy), holding that aerial observations and surveys of a large industrial plant were constitutionally permissible even in the absence of a warrant.

18. In United States v. Jamieson-McKames, 651 F.2d at 540, the court concluded that the FDA can apply for, and obtain, an inspection warrant even though the Act makes no explicit provision for such a warrant. In Boliden Metech, Inc. v. United States, 695 F. Supp. 77 (D.R.I. 1988), the court reached a similar conclusion under the Toxic Substances Control Act, Pub. L. No. 94-469, § 11, 90 Stat. 2032 (1976) (codified at 15 U.S.C. § 2610 (1982)). But see Matter of Establishment Inspection of Skil Corp., 846 F.2d 1127, 1130 (7th Cir. 1988) (and the cases cited therein) where the court treated an inspection warrant issued under the Consumer Product Safety Act, Pub. L. No. 92-573, § 16, 86 Stat. 1222 (1972) (codified at 15 U.S.C. § 2065(b) (1982)), as an injunction and noted what the court perceived to be the minimal difference between an injunction and an inspection warrant, particularly insofar as the government had failed to summarily execute the warrant. Nevertheless, the court found the Commission's demand for documents in that case to be reasonable. *Id.* at 1134.

19. The Civil Division represents the FDA in all civil and criminal litigation under the Act and the other statutes the FDA enforces, 28 C.F.R. § 0.45(j) (1988).

warrant. In essence, an analysis is done of the legal sufficiency of the evidence. An assessment is made of the FDA's prior efforts to inspect. Factors considered include the reasons given by the firm's representative for refusing the inspection and whether the prior attempts were made at reasonable times. The OCL also considers the scope of the proposed inspection as set out in the application for a warrant, taking into account the following issues, among others.

A. *The Establishment*

Section 374(a)(1) permits employees of the FDA, upon presenting appropriate credentials and a written notice, to enter, at reasonable times, any establishment in which foods, drugs, devices, or cosmetics are manufactured, processed, packed, or held (as well as the vehicles used to transport these items), and to inspect, at reasonable times, within reasonable limits, and in a reasonable manner, such facility and all pertinent equipment, materials, containers, and labeling. The statute does not limit the area of the premises that may be inspected.

Under statutes that require a warrant as a predicate after a firm's refusal to consent to an administrative inspection, a firm chosen for an inspection on the basis of a general administrative plan for the enforcement of a statute, as derived by neutral sources, is subject to a "general" inspection warrant.[20] Therefore, an inspection of the entire workplace is permissible where probable cause is established by a reasonable legislative or administrative plan. As noted earlier, the FDA has the statutory right to inspect absent a warrant and need not have a "general administrative plan" in place. The courts have differed, however, as to whether inspection warrants issued to other federal agencies in response to specific complaints, must be limited in scope to the complaints' subject matter. A number of courts have held that a specific employee complaint automatically supports inspection of a company's entire workplace.[21]

It is the view of the Department of Justice that FDA-initiated inspec-

20. *See* Marshall v. North Am. Car Co., 626 F.2d 320, 323 (3d Cir. 1978).

21. *See* Donovan v. Burlington Northern, Inc., 694 F.2d 1213, 1215 (9th Cir. 1982), *cert. denied*, 463 U.S. 1207 (1983); Hern v. Iron Works, 670 F.2d 838, 841 (9th Cir.), *cert. denied*, 459 U.S. 830 (1982); In re Establishment of Seaward Int'l, Inc., 510 F. Supp. 314 (W.D. Va. 1980), *aff'd mem.*, 644 F.2d 880 (4th Cir. 1981); Burkhart Randall Div. of Textron, Inc. v. Marshall, 625 F.2d 1313, 1324-25 (7th Cir. 1980) (and cases cited therein) (holding that where probable cause to conduct an Occupational Safety and Health Administration (OSHA) inspection is on the basis of an employee complaint, the inspection need not be limited to the area of the complaint). *Compare* In re Inspection of Workplace, 741 F.2d 172 (8th Cir. 1984) (and cases cited therein); Donovan v. Fall River Foundry Co., Inc., 712 F.2d 1103, 1107-08 (7th Cir. 1983) ("*Burkhart Randall* cannot properly be read, however, as holding that employee complaints *always* justify issuance of a full-scale warrant.") (emphasis in original); and Marshall v. North Am. Car Co., 626 F.2d at 323 (3d Cir. 1978). The Act, unlike the statute under which OSHA operates (29 U.S.C. § 657), has one provision that covers "routine" as well as complaint-generated inspections. As a result, the statutory scheme under which the FDA operates does not permit a distinction between these two types of inspections in terms of the breadth of the inspection.

tions, limited only to the area of the plant involved in employee or other complaints, do not advance the broad remedial purpose of the Act because employers may be able to present sanitized areas to the inspectors while concealing violations elsewhere on the premises. Furthermore, considerations of administrative efficiency and minimizing repeated disruptions of a plant's operations indicate that a general inspection is preferable to a number of separate, limited inspections.

B. *Books and Records*

The FDA's statutory authority to conduct nonconsensual inspections of books and records is more limited than its authority to inspect the business establishment. Warrant applications are confined to those books and records that the law authorizes the FDA to inspect.

Under section 374(a)(1), "[i]n the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs or restricted devices are manufactured, processed, packed, or held, the inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities)" bearing on whether prescription drugs[22] or restricted devices[23] are adulterated or misbranded. The section further states that no inspection authorized for prescription drugs or restricted devices "shall extend to financial data, sales data other than shipment data, pricing data, personnel data . . . , and research data . . . ."[24] Section 374(a)(2)(B) also excludes persons such as certain practitioners licensed to prescribe or administer drugs from an inspection by the FDA of identified records.[25]

The FDA also has authority to inspect and copy records relating to testing conducted during the manufacture of "new drugs."[26] In addition, records on medical device manufacture, testing, and distribution are required to be maintained,[27] and, therefore, are subject to inspection and copying pursuant to section 374(e). The regulations provide that "[a]fter a device has been released for distribution, any failure of that device or any of its components to meet performance specifications shall be investigated. A written record of the investigation, including conclusions and follow up,

22. A recent case, United States v. Burka, 700 F. Supp. 825 (E.D. Pa. 1988), sustained the DEA's ability to conduct an administrative inspection of a doctor's records pursuant to a warrant issued under the Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, title II, § 510, 84 Stat. 1274 (codified at 21 U.S.C. § 880).

23. See Matter of Establishment Insp. Portex, 595 F.2d 84 (1st Cir. 1979) which held, in the context of an FDA inspection warrant for records, that endotracheal tubes were not "restricted devices."

24. Pub. L. No. 75-717, § 704, 52 Stat. at 1057, as amended 21 U.S.C. § 374(a)(1)(B).

25. But see United States v. Jacobs, Food Drug Cosm. L. Rep. (CCH) ¶ 38,123 (E.D. Cal. 1989), where the court held that the defendant had "consented" to such an inspection.

26. 21 U.S.C. § 355(k)(2) and 21 C.F.R. § 312 (1988). *See* Leo Winter Assocs. v. Department of HHS, 497 F. Supp. 429 (D.D.C. 1980) (applying that regulation to a "contract research organization").

27. 21 U.S.C. § 360i.

shall be made."[28] Section 374(a)(3) pertains to inspections of records relating to infant formula.[29]

The FDA also has statutory authority to inspect and copy records relating to the interstate movement of foods, drugs, devices, and cosmetics.[30] However, the inspected firm may insist that a request for such records be in writing. A written request, however, confers "immunity" from criminal prosecution based on the evidence so obtained.[31] As a result, FDA employees are generally unwilling to make a written request for records in this situation.

C. *Samples*

The taking of samples is explicitly permitted by the Act.[32] Thus, FDA inspection warrants often specifically authorize collection of samples from the inspected firm.

D. *Photographs*

The Department of Justice is of the view that the FDA has a right to take photographs during an inspection as long as the inspectors are following the requirements mandated by section 374 or another pertinent statute enforced by the FDA. In 1986, the FDA published a revised Inspection Operations Manual to detail the agency's current policies concerning photos to be taken during inspections.[33] The FDA's interpretation of section 374 is consistent with the agency's long-standing understanding of this provision.

No one has ever seriously questioned an FDA inspector's right to ob-

---

28. 21 C.F.R. § 820.162. Courts have interpreted that regulation as requiring production of the total written record of a "failure" investigation, including supporting documents such as lab notes, x-rays, and other documents. "Congress recognized that reasonable record keeping requirements could include 'reporting defects, recalls, adverse reactions, patient injuries, and clinical experience' with regard to medical devices." In re Medtronic, Inc., 500 F. Supp. 536, 539 (D. Minn. 1980) (emphasis omitted). *See also* Becton Dickinson & Co. v. FDA, 448 F. Supp. 776, 778-79 (N.D.N.Y.), *aff'd*, 589 F.2d 1175 (2d Cir. 1978).

29. 21 U.S.C. § 350a. The courts have recently become embroiled in the question of OSHA's ability to obtain records without a warrant. In Brock v. Emerson Elec., 834 F.2d 994 (11th Cir. 1987), the court held unconstitutional, on fourth amendment grounds, a regulation permitting OSHA to inspect employers' records without either a warrant or a subpoena. However, in McLaughlin v. A.B. Chance Co., 842 F.2d 724, 728 (4th Cir. 1988), the Fourth Circuit disagreed with *Emerson*, holding that, due to the regulation at issue, the company from which the records were sought had no reasonable expectation of privacy. A third decision, McLaughlin v. Kings Island, 849 F.2d 990, 995 (6th Cir. 1988) followed *Emerson* and declined to follow *A.B. Chance*. See also United States v. Stanack Sales Co., 387 F.2d 849 (3d Cir. 1968), where the court reversed convictions under 21 U.S.C. § 331(f) for refusal to disclose records in an FDA inspection and held that the FDA needed a subpoena to get the records.

30. Pub. L. No. 75-717, § 703, 52 Stat. at 1057, as amended 21 U.S.C. § 373.

31. *Id.*

32. *Id.* §§ 702(b), 704, 52 Stat. at 1056, 1057, as amended 21 U.S.C. §§ 372(b); 374(c), (d). United States v. Roux Laboratories, Inc., 456 F. Supp. 973, 975 (M.D. Fla. 1978) (and the cases cited therein).

33. FDA Inspection Operations Manual § 523 (1986).

serve and to record inspection findings even though the Act does not specifically authorize an inspector to write notes of his observations. Photographs are simply a shorthand, and highly accurate, way of reporting the findings. They record what the investigator has observed, without the possibly subjective intervention of the viewer's tone or vocabulary.

Taking photographs by FDA investigators is within the scope of section 374. Explicit statutory authority for photography is not required. The primary purpose of the Federal Food, Drug, and Cosmetic Act is to prevent injury to the public health and safety through the sale and transportation of misbranded and adulterated articles in interstate commerce.[34] Photographs taken by FDA inspectors to document accurately the conditions observed furthers the purposes of the Act.

1. *The* Dow *Decision*

The Supreme Court has held that the Environmental Protection Agency (EPA) has inherent authority to take photographs pursuant to the Clean Air Act.[35] In *Dow Chemical Co. v. United States*,[36] the Court held that the use of aerial observation and photography by the EPA was permitted pursuant to the nonrestrictive, but inexplicit, statutory language of the Clean Air Act. The Court determined that Congress empowers a regulatory agency to utilize "all the modes of inquiry and investigation traditionally employed or useful to execute the authority granted."[37] While four of the Justices dissented from part of the Court's opinion, all nine Justices joined the opinion of the Court in the section dealing with the EPA's statutory authority.

In *Dow*, the company maintained elaborate security to bar public observation of its facility. The company denied an EPA request for an on-site inspection of the plant. Thereafter, the EPA investigators did not seek an administrative warrant, but, instead, utilized a commercial aerial photographer, flying within lawfully navigable airspace, to photograph the plant. In considering whether the EPA had exceeded its authority, the Supreme Court held that the utilization of aerial observation and photography was encompassed in the EPA's general statutory investigatory authority which, like the FDA's, does not purport to list all permissible means of inspection.[38] The Court determined that "it is not necessary to identify explicitly

34. United States v. Dotterweich, 320 U.S. 277 (1943).
35. 42 U.S.C. §§ 7413-7414.
36. 476 U.S. 227 (1986).
37. *Id.* at 233.
38. *Id.* The *Dow* Court noted that an actual physical entry by the EPA into an enclosed area would have raised significantly different questions because, citing See v. City of Seattle, 398 U.S. 541, 543 (1967), businessmen have a constitutional right to do business free from unreasonable entries upon private property. *Id.* at 236-37. However, courts have held that the EPA (unlike the FDA) cannot compel warrantless inspections of business premises under the statute at issue in *Dow*. Public Serv. Co. of Indiana, Inc. v. United States EPA, 509 F. Supp. 720, 722-23 (S.D. Ind. 1981), *aff'd on other grounds*, 682 F.2d 626 (7th Cir. 1982), *cert. denied*, 459 U.S. 1127 (1983). Thus, the Court's

each and every technique that may be used in the course of executing the statutory mission."[39]

The *Dow* Court reasoned that common sense and ordinary human experience dictate how a law will be enforced.[40] It analogized the EPA's authority to that of the police.[41] The Court noted that a legislature need not approve the police's authority to conduct aerial observation for the purpose of traffic control; thus, those things that the government investigator can observe may also be photographed, particularly where photographs have been shown to have "enhanced law enforcement techniques."[42]

2. *Courts have held that Section 374 Authorizes the Use of Photographs by FDA Inspectors*

Courts have explicitly concluded that photographs are a reasonable, and legally acceptable, means of inspection by the FDA.[43] These cases are consistent with the principle of statutory construction that "remedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health."[44] Similarly, courts have rejected other attempts to construe

---

discussion is not applicable to an FDA inspection where the inspector is photographing the business premises that an inspector can lawfully inspect (with or without a warrant) under section 374.

39. *Id.*

40. *Id.*

41. *Id.*

42. *Id.* at 231. In one of the few cases that have applied *Dow*, a district court held that the Toxic Substances Control Act permits the EPA to take photographs, thereby rejecting the plaintiff's argument that the agency lacked that authority because the statute did not explicitly permit the taking of photographs. Boliden Metech, Inc. v. United States, 659 F. Supp. 77, 81 (D.R.I. 1988).

43. United States v. Gel Spice Co., Inc., 601 F. Supp. 1214, 1220 (E.D.N.Y.) (adopting recommendation of the magistrate, who had concluded that section 374 "provides a flexible standard of reasonableness to define the contours of an FDA inspection" and that, therefore, photographs were lawfully taken as part of the inspection), *aff'd on other grounds*, 773 F.2d 427 (2d Cir. 1985), *cert. denied*, 474 U.S. 1060 (1986); United States v. Acri Wholesale Grocery Co., 409 F. Supp. 529, 533 (S.D. Iowa 1976); United States v. Jamieson-McKames Pharmaceutical, Inc., No. 77-131 CR (3) (E.D. Mo. 1979) (rejecting defendants' claim that section 374 does not authorize photographs and concluding that the defendants had the opportunity to explain (in a motion to quash filed in the criminal action) their contention that the photographs were not a true and accurate depiction of the inspected premises), *aff'd in part and remanded in part on other grounds*, 651 F.2d 532 (8th Cir. 1981), *cert. denied*, 455 U.S. 1016 (1982). One court also declined to prohibit the FDA's practice of taking photographs. Durovic v. Palmer, 342 F.2d 634, 637 (7th Cir.), *cert. denied*, 382 U.S. 820 (1965).

The *Acri* court rejected the defendants' argument that "photographic activities were outside the scope of 21 U.S.C. § 374(a)," 409 F. Supp. at 532, and concluded that "[p]ursuant to Section 374(a), a flexible standard of 'reasonableness' defines the contours of an FDA inspection." *Id.* at 533. Accordingly, both the magistrate and the district court determined that the photographing of warehouse conditions by the FDA's agents was not unreasonable. The court noted that the agents possessed lawful authority to be in the warehouse, had followed all procedural requirements mandated under section 374, and had made no efforts to conceal the fact that photographs were being taken. Finally, the court rejected the defendants' fourth amendment argument concerning the photos, concluding that "as previously discussed, the FDA agents were properly acting pursuant to statutory procedures." *Id.*

44. United States v. An Article of Drug . . . Bacto-Unidisk, 394 U.S. 784, 798 (1969).

narrowly the inspection powers given by Congress to the federal government when it seeks to protect the public health and safety.[45]

3. *Congress Purposely did not Identify Each and Every Technique the FDA Could Utilize for Investigating and Enforcing the Act*

The relevant language of section 374(a)(1) was enacted by Congress in 1953.[46] Section 374(a)(1) had previously required the FDA to obtain permission to inspect from the firm to be inspected. The Supreme Court found the statute unconstitutional because of an internal inconsistency in the Act.[47] The public outcry was immediate and dramatic. President Dwight D. Eisenhower's 1953 State of the Union Address called for Congress to enact "promptly" legislation to permit the FDA to continue its program of inspecting business establishments.[48]

The House Interstate and Foreign Commerce Committee held hearings on three bills intended to restore the FDA's inspection powers. The committee understood that the FDA was routinely taking photographs as part of its inspection program.[49] Indeed, Congressman Joseph P. O'Hara, one of the opponents of the legislation, questioned the FDA Commissioner about the agency's statutory authority to take photographs.[50] Then-Commissioner Charles W. Crawford replied that the FDA had authority under section 374 (even prior to the 1953 amendment that broadened the FDA's authority) to take photographs, although he readily admitted that the statutory language did not explicitly confer that authority.[51] The chairman of the committee considering the legislation, Representative Charles A. Wolverton, was present when Commissioner Crawford made these statements.[52] Chairman Wolverton replied:

> The failure to include a minute description of every power that

45. In Brock v. Nabisco Brands, Inc., 12 O.S.H. Cas. (BNA) 1753 (W.D.N.Y. 1986), the court ordered Nabisco to allow OSHA inspections, specifically including photographs, to ensure safe and healthful working conditions. In Public Serv. Co. of Indiana v. United States EPA, 509 F. Supp. 720, 725-29 (S.D. Ind. 1981), *aff'd*, 682 F.2d 626, 638 (7th Cir. 1982), *cert. denied*, 459 U.S. 1127 (1983), the court upheld the EPA's right to take photographs of the plaintiff's generating facilities and rejected the assertion that the EPA had no statutory authority to photograph. *See also* Service Foundry Co., Inc. v. Donovan, 721 F.2d 492, 496-97 (5th Cir. 1983) (dismissing the plaintiff's argument that OSHA could not use personal sampling devices, although plaintiff had asserted, correctly, that OSHA's enabling statute did not explicitly provide for such a device to be used in an inspection). *Accord* Donovan v. Enterprise Foundry, Inc., 751 F.2d 30, 36-37 (1st Cir. 1984).

46. Pub. L. No. 83-217, 67 Stat. 476 (1953).

47. United States v. Cardiff, 344 U.S. 174 (1952). The Court held that while the Act allowed an establishment to refuse an FDA "request" to conduct an inspection, another provision of the Act made it a crime to refuse such a request. Presently, section 374 does not condition the FDA's right to inspect on an establishment's explicit consent.

48. *See Food, Drug, and Cosmetic Act (Factory Inspections): Hearings on H.R. 2769 et al. Before the House Comm. on Interstate and Foreign Commerce*, 83d Cong., 1st Sess. 2 (1953).

49. *See, e.g., id.* at 24.

50. *Id.* at 93-94.

51. *Id.* at 94.

52. *Id.* at 96.

> you have is not due, I take it, to any lack of intention or desire on the part of the Congress for you to have and exercise that authority. My own personal opinion is that the act was passed by the Congress in the interest of the welfare of the people. Therefore it must be assumed that the Department may use all reasonable means to carry out what was the purpose of Congress in passing the act.
>
> I would hate to see the time come when it was necessary for the Congress to write into the law every last detail of your activity . . . .[53]

When the committee subsequently reported a bill to amend the FDA's inspection authority,[54] the committee rejected efforts to spell out specific limitations on the FDA's authority. Rather, the committee employed general limiting language, "within reasonable limits and in a reasonable manner," thereby leaving the FDA to determine the meaning of that language.[55] Thus, the committee did not prohibit the FDA from continuing its practice of taking photographs during inspections.[56]

The Senate Committee on Labor and Public Welfare, which subsequently considered the same bill, also refused to limit the FDA's inspection authority, noting, "The bill is not specific in spelling out exactly what would be reasonable in any and all circumstances. Such a detailed specification would be impossible. The general rule of reasonableness, used in the bill, however, seems eminently fair both to the public and to private business."[57] The committee determined that "[w]hat is reasonable, of course, depends on the circumstances of the specific case, and hard and fast rules cannot be laid down."[58]

In sum, the legislative history of the 1953 amendments to section 374(a) shows that Congress was well aware that the FDA routinely took photographs in its administrative inspections. Congress did not prohibit that

---

53. *Id.*

54. H.R. 5740, 83d. Cong., 1st Sess. (1953).

55. H.R. REP. NO. 708, 83d Cong., 1st Sess. 7 (1953).

56. *See also* the floor debates where Rep. Wolverton stated the committee had rejected the minority's efforts to limit carefully the inspection powers given to the FDA: "I believe that we must place some degree of trust in the agency which is called upon to exercise these powers." 100 CONG. REC. 8999 (1953).

57. S. REP. NO. 712, 83d Cong., 1st Sess. 4 (1953).

58. *Id.* In the late 1970s, as part of the legislation intended to amend many portions of the Act, there were efforts explicitly to authorize the FDA to take photos during administrative inspections. *See, e.g.*, H.R. 11,611, 95th Cong., 2d Sess. § 175 (1978); S. 2755, 95th Cong., 2d Sess. § 175, 124 CONG. REC. 7227 (1978). However, those proposals were simply efforts to codify existing law. *See Drug Regulation Reform Act of 1978: Hearings on H.R. 11,611 Before the Subcomm. on Health and the Environment of the House Comm. on Interstate and Foreign Commerce*, 95th Cong., 2d Sess. 513 (1978). Indeed, the FDA's Chief Counsel, Richard M. Cooper, stated that the FDA already had statutory authority to take photographs during an inspection and that the legislation simply would expressly so state. *Food Safety and Nutritional Amendments of 1978: Hearings Before the Subcomm. on Health and the Environment of the House Comm. on Interstate and Foreign Commerce*, 95th Cong., 2d Sess. 317 (1978).

practice.[59] Rather than giving a detailed specification of what was "reasonable" in all circumstances, Congress left to the FDA (and the possible judicial review by courts) the determination of whether the taking of photographs is reasonable under the statutory language, carefully chosen by Congress, that requires an inspection to be conducted "within reasonable limits and in a reasonable manner."[60]

4. *Photographs do not Constitute an Unreasonable Search and Seizure Because the FDA Utilizes Methods of Observation Commonly Available to the Public*

Generally, FDA investigators do not utilize anything more sophisticated than a 35-mm camera to photograph facilities. In *Dow*, the Court held that aerial photography was not an unreasonable search and seizure, in part because the EPA did not employ "unique sensory device[s]" or "sophisticated surveillance equipment not generally available to the public."[61] The Court reached this conclusion even though it understood that the photographs at issue gave the government more detailed information than would have been available to the human eye.[62] The FDA's photographs similarly are not so detailed and "sophisticated" as to raise constitutional concerns. The photographs are no more intrusive than the trained observations of an experienced investigator.

The FDA's employment of photographs during inspections is, in one sense, even less intrusive than the photography permitted in *Dow*. The FDA photographs are taken after the inspector presents to the person in charge of the plant the inspector's FDA credentials and a notice of inspection.[63] The inspected business knows, therefore, that the inspector is in the plant and may take photographs of what is observed. Clearly, the business being inspected cannot have *any* expectation of privacy concerning photographs that are taken by an FDA inspector during an inspection that is

59. In contrast, in 1953, Congress placed other limits on the FDA's inspection practices. It mandated that each FDA "inspection shall be commenced and completed with reasonable promptness." Pub. L. No. 83-217, 67 Stat. at 477. This demonstrates that when Congress intended to limit inspections it explicitly did so; it also revealed a congressional concern for prompt completion of inspections. Photographs, which can be taken quickly by a photographer such as an FDA inspector, better serve that goal than either sketches or laborious written descriptions of the inspector's observations.

60. *Id.* No serious argument can be made that the taking of photographs would result in the disclosure of the inspected firm's trade secrets. *See* 21 C.F.R. §§ 20.20-.32; *see also* 21 U.S.C. § 331(j). Indeed, when Congress passed the 1953 amendment, it understood that then-existent FDA regulations would protect a firm being inspected from improper disclosure by the FDA of trade secret information. S. REP. No. 712, 83d Cong., 1st Sess. 4 (1953). Furthermore, courts have dismissed arguments that an inspection conducted by a regulatory agency was unlawful because the agency might disclose trade secrets. *See, e.g., Dow*, 476 U.S. at 231-32, 234 n.2 ("[g]overnments do not generally seek to appropriate trade secrets of the private sector, and the right to be free of appropriation of trade secrets is protected by law"); and Bunker Hill Co. v. EPA, 658 F.2d at 1284.

61. 476 U.S. at 238. Indeed, the $20,000 aerial mapping camera used in *Dow* was much more sophisticated than the cameras the FDA uses.

62. *Id.*

63. Pub. L. No. 75-717, § 704, 52 Stat. at 1057, as amended 21 U.S.C. § 374(a).

conducted with the full knowledge of the business. In contrast, the Court rejected Dow's claim that the EPA's "unannounced" aerial surveillance deprived the company of its "right" to know that an inspection was being conducted.[64]

E. *Form Matters*

The final review by the OCL is to determine if the application and warrant comply with the forms that have been agreed upon by the Department of Justice and the FDA in conformity with existing law and common procedure in the courts. A number of form questions are included here, although this list is not exhaustive. The application generally is entitled "In the Matter of Establishment Inspection of ABC Co."—not "United States v. ABC Co." Although the application may be to either a United States magistrate or a United States district court judge, the former is the preferred procedure. A miscellaneous or magistrate's number is put on the papers, not a civil action number. Specific authority permitting a Deputy United States Marshal to accompany the FDA inspector to the site is often included in warrant applications. This is particularly necessary if the FDA expects the firm to resist execution of the warrant. Such resistance may be a crime.[65]

IV. Coordination with United States Attorneys' Offices

After review is completed by the OCL, the papers to be filed are sent by the FDA to the United States Attorney's office for the jurisdiction where the premises to be inspected are located. The FDA investigator or compliance officer will then provide any further information the Assistant United States Attorney requires. The application for a warrant is then made, in writing, by a representative of the FDA and is signed by an FDA compliance officer or investigator in the presence of a magistrate. The FDA official is normally accompanied by an Assistant United States Attorney or an OCL attorney. Occasionally, the application will include an affidavit from the FDA explaining why the warrant is necessary.

The application procedure is *ex parte*. It is inappropriate, and against Civil Division policy, to turn the application proceeding into a contested hearing.[66] If hearings are contested, the additional litigation would under-

64. 476 U.S. at 234.

65. *See* 18 U.S.C. §§ 1501, 1505, 1509.

66. Marshall v. Barlow's, Inc., 436 U.S. at 316-17 (a court has the power to issue an inspection warrant following an *ex parte* application); Marshall v. Milwaukee Boiler Mfg. Co., Inc., 626 F.2d 1339, 1345-46 (7th Cir. 1980) ("the agency is not required to make a massive evidentiary showing of particularized cause and a simple warrant request hearing should not be turned into a full-blown hearing"); Pelton Casteel, Inc. v. Marshall, 588 F.2d 1182, 1186 (7th Cir. 1978) (holding that a United States magistrate has the power to issue an inspection warrant following an *ex parte* application); *accord* Donovan v. Red Star Marine Servs., Inc., 739 F.2d 774 (2d Cir. 1984), *cert. denied*, 470 U.S. 1003 (1985); Rockford Drop Forge v. Donovan, 672 F.2d 626 (7th Cir. 1982); In re Estab-

mine the speedy and efficient implementation of the Act, and require an unwarranted consumption of enforcement energies that would exceed manageable proportions. Indeed, the essence of the Act requires that warrants be issued *ex parte* and executed without delay or prior notice in order to preserve the element of surprise, thus avoiding alterations and disguises of violations from FDA inspectors.[67]

V. The Justice Department's Role if Inspection Pursuant to a Warrant is Refused

The warrant, once signed by the United States magistrate, is a court-ordered authorization to conduct an administrative inspection. Refusal by an establishment to comply with an inspection warrant is immediately reported to the OCL by the FDA and the local United States Attorney's office. After the three entities have consulted, a determination is made as to the appropriate remedy unless otherwise determined prior to the refusal.

A. *The Use of Physical Force as an Enforcement Tool in Executing Inspection Warrants*

Although the Act does not specifically authorize the use of forcible entry under section 374,[68] case law provides support for such action by a Deputy United States Marshal.

Section 374 of the Act is somewhat analogous to the inspection provision found in the Occupational Safety and Health Act of 1970, which authorizes the Occupational Safety and Health Administration (OSHA) "to enter without delay and at reasonable times" any workplace and "inspect and investigate" the workplace.[69] It differs, however, in that OSHA, unlike the FDA, must (absent consent or some other exception) obtain a warrant prior to conducting an inspection. The Fifth Circuit has ad-

---

lishment Inspection of Keokuk Steel Castings, 638 F.2d 42 (8th Cir. 1981); In re Chicago Aluminum Castings Co., Inc., 535 F. Supp. 392, 396 (N.D. Ill. 1981) (a "hearing on an application for a search warrant is not and never has been an adversary proceeding"); Stoddard Lumber Co., Inc. v. Marshall, 627 F.2d 984 (9th Cir. 1980).

There is some authority holding that applications cannot be *ex parte* if the agency does not have regulations allowing for such (which the FDA does not have). *See, e.g.*, Smith Steel Casting Co. v. Donovan, 725 F.2d 1032 (5th Cir. 1984); Cerro Metal Prods. v. Marshall, 467 F. Supp. 869 (E.D. Pa. 1979), *aff'd*, 620 F.2d 964 (3d Cir. 1980). However, these cases do not relate to an agency, such as the FDA, that can constitutionally mandate an inspection without a warrant.

67. See Skinner v. Railway Labor Executives' Ass'n, 109 S. Ct. 1402, 1416 (1989), where the Court upheld drug testing without a warrant, stating that the "delay necessary to procure a warrant nevertheless may result in the destruction of valuable evidence."

68. "The bill authorizes entry and inspection but does not authorize the inspector to enter the establishment by force." S. Rep. No. 712, 83d Cong., 1st Sess. 4, *reprinted in* 1953 U.S. Code Cong. & Admin. News 2198, 2201. *See also* H. Rep. No. 708, 83d Cong., 1st Sess. 5 (1953), and United States v. Jamieson-McKames Pharmaceuticals, Inc., 651 F.2d 532 (8th Cir. 1981), *cert. denied*, 455 U.S. 1016 (1982).

69. Pub. L. No. 91-596, § 8, 84 Stat. 1598 (codified at 29 U.S.C. § 657(a)).

dressed the use of physical force to execute an inspection warrant.[70] The court had before it a request by OSHA to obtain an injunction to order the appellees to allow an inspection pursuant to an already-obtained inspection warrant. In denying OSHA's request, the court noted the presumption that "Congress, desiring an enforcement scheme based on surprise and undelayed searches, would very much prefer immediate execution of duly-issued *ex parte* warrants to the litigation-ladened delays urged on us by the search-shy Secretary in this case."[71] The court explained its reasoning by noting that an injunction to enforce a warrant is "redundant": "We see a search warrant as a full and complete judicial authorization for a search . . . . If necessary, physical force is available for the execution of the warrant."[72]

The Civil Division policy is to seek immediate assistance from United States Marshals to gain entry, using physical force if necessary, to accomplish a court-ordered inspection. The recent inspection warrants issued to the FDA have authorized a Deputy United States Marshal to accompany the FDA inspector in executing the warrant. A Deputy United States Marshall has the right to use physical force to execute a court-issued warrant.[73] Thus, United States Marshals can summarily carry out duly-authorized inspection warrants.

Obviously, the use of physical force to effectuate a warrant is not to be undertaken lightly. There are, however, circumstances where delay upon refusal to honor a warrant cannot be tolerated if the agency is to carry out its mission of protecting the public health. The FDA guidelines presently state that when a firm refuses to honor a warrant, summary execution of the warrant by a United States Marshal is the preferred vehicle for gaining admission to the premises.[74]

B. *Civil Contempt Proceedings*

Refusal to allow an inspection authorized by a warrant issued by a United States magistrate is also considered contempt of court.[75] Thus, by

---

70. Marshall v. Shellcast Corp., 592 F.2d 1369 (5th Cir. 1979).

71. *Id.* at 1372.

72. *Id.* at 1372 n.7; *see also* See v. City of Seattle, 387 U.S. at 545 ("administrative entry, without consent, upon the portions of commercial premises which are not open to the public may . . . be compelled through . . . *physical force* within the framework of a warrant procedure") (emphasis added); United States v. Mississippi Power & Light Co., 638 F.2d 899, 907 (5th Cir.), *cert. denied*, 454 U.S. 892 (1981); and United States v. Kramer Grocery Co., 418 F.2d 987, 988 n.2 (8th Cir. 1969).

73. 18 U.S.C. § 3109.

74. FDA Inspection Operations Manual § 514.12 (1987). However, as noted earlier, well over ninety-nine percent of those inspections attempted by the FDA have been conducted pursuant to the agency's statutory authority, without the firm setting up meritless roadblocks.

Once the warrant is fully executed, a court lacks jurisdiction to quash the warrant in a lawsuit seeking such relief. *See* B & B Chemical Co. v. United States EPA, 806 F.2d 987 (11th Cir. 1986); and Marshall v. Central Mine Equip. Co., 608 F.2d 719 (8th Cir. 1979).

75. *See, e.g.*, Marshall v. Shellcast Corp., 592 F.2d at 1372 n.7; United States v. Roux Laboratories, Inc., 456 F. Supp. at 978; and In re Mallard Beauty Prods., Inc., Civ. No. 79-0020H (S.D.

choosing to refuse to comply with an inspection warrant, a firm runs the risk of being held in civil contempt.[76] The fine for a civil contempt may be levied not only to motivate the party to obey the court's order,[77] but also to compensate for losses and expenses, including attorneys' fees, incurred by the government because of the disobedience.[78] More significant, a party in civil contempt may be imprisoned until purged of the contempt. Finally, good faith is not a defense in refusing to honor an inspection warrant and will not prevent a defendant from being held in civil contempt.[79]

Civil contempt charges are filed with either a magistrate,[80] or a district court judge, and ask the court to order the respondent to show cause why it should not be held in civil contempt. If the application is originally made to a magistrate, he can certify appropriate facts and schedule a hearing before a district judge.

C. *Criminal Contempt Proceedings*

Criminal contempt proceedings may be appropriate where a person has willfully failed to honor a warrant.[81] This remedy provides for punishment only and does not seek to order the firm to allow an inspection. Federal law does not place any limit on the length of imprisonment or amount of fine that the court may impose.

VI. Conclusion

The Federal Food, Drug, and Cosmetic Act protects the public health and safety by prohibiting the manufacture and distribution of adulterated and misbranded foods, drugs (including unapproved new drugs), cosmetics, and devices. It is the responsibility of the OCL, working in conjunction with the FDA and United States Attorneys' offices, to make sure this law is effectively enforced. An administrative inspection is the primary statutory tool available to the FDA to ensure compliance with the Act so that the health and safety of the American public is never compromised. With this in mind, the Department of Justice stands prepared to do eve-

---

Ala. 1979).

76. Donovan v. Trinity Indus., Inc., 824 F.2d 634, 638 (8th Cir. 1987) (plant managers properly held in contempt of court even though they "were merely performing a service for the corporation"); Donovan v. Hackney, Inc., 769 F.2d 650, 654 (10th Cir. 1985), *cert. denied*, 475 U.S. 1081 (1986); and Babcock and Wilcox Co. v. Marshall, 610 F.2d 1128, 1136 (3d Cir. 1979).

77. Shillitani v. United States, 384 U.S. 364, 368 (1966); McComb v. Jacksonville Paper Co., 336 U.S. 187, 191 (1949); and Southern Railway Co. v. Lanham, 403 F.2d 119, 124 (5th Cir. 1968).

78. Donovan v. Burlington Northern, Inc., 781 F.2d 680 (9th Cir. 1986); Donovan v. Hackney, Inc., 769 F.2d at 654.

79. Donovan v. Enterprise Foundry, Inc., 751 F.2d 30, 38 (1st Cir. 1984) (and cases cited therein).

80. Pursuant to 28 U.S.C. § 636(e).

81. 18 U.S.C. § 401(3). *See* Becton, Dickinson & Co. v. FDA, 448 F. Supp. at 780 n.6., and In the Matter of Edward F. Devitt, No. 75 M 181 (N.D. Ill. 1975). *See also* United States v. I.D. Russell Laboratories, 439 F. Supp. at 717-21.

rything within its legal authority to ensure that administrative inspections are carried out efficiently and without delay.