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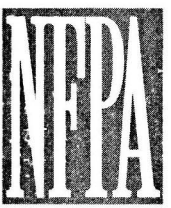
FDA Factory Inspection Authority

Under the Federal Food, Drug, and Cosmetic Act

BULLETIN 39-L



NATIONAL FOOD PROCESSORS ASSOCIATION

Preface

Bulletin 39-L was prepared by NFPA legal counsel, Covington & Burling. The first edition of the Bulletin was published in March 1978. This is an expanded and updated version, reflecting significant court decisions and changes in FDA inspection policy since 1978, and including a detailed index and annotation. This *Bulletin* is designed to provide general information and guidelines regarding Federal Food and Drug Administration (FDA) food plant inspections. Firms using this *Bulletin* should seek their own individual legal and technical guidance to deal with specific inspection situations.

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FDA RIGHT OF INSPECTION

1. *FDA inspectors are entitled as a matter of right to enter and inspect "any factory, warehouse, or establishment in which food... (is) manufactured, processed, packed, or held for introduction into interstate commerce."*

In 1953, following a Supreme Court decision denying FDA inspectors a compulsory right of access to food and drug plants (United States v. Cardiff, 344 U.S. 174 (1952)), Congress amended Section 704 of the FD&C Act to grant to FDA a compulsory right of entry to food and drug plants. The consent of the owner or operator of the plant is not required.

(a) *FDA inspectors have this right of entry even without a search warrant.*

Courts have held that warrantless inspections conducted by FDA under Section 704 are valid and are not prohibited by the Fourth Amendment's ban on unreasonable searches and seizures on the theory that the inspections are specifically authorized by statute, are carefully limited in scope, are in furtherance of an urgent federal interest (food safety), and involve a pervasively regulated area in which there can be little expectation of privacy. United States v. Gel Spice Co., Inc., 601 F. Supp. 1214 (E.D. N.Y. 1985).

(b) *If an owner or operator of a food plant refuses to permit an FDA inspector to enter or inspect the plant, the official and the company may be prosecuted under the criminal provisions of the Act.*

Section 301(f) of the Act prohibits the refusal to permit entry or inspection as authorized by Section 704, and Section 303(a) of the Act provides that any person who is found to have violated a provision of Section 301 shall be imprisoned for not more than one year or fined, or both.

(c) *If entry to a plant is refused, an FDA inspector is empowered to obtain a search warrant to gain access to the facility.*

FDA inspectors are instructed to obtain a search warrant if they are denied access to a food plant or warehouse. On rare occasions an inspector may obtain a search warrant for his first visit to a plant if he has any reason to expect that he might be denied entry or where surprise is essential. Refusal to permit entry to an inspector with a search warrant will almost certainly result in criminal prosecution.

(d) *FDA inspectors are instructed not to use force or harassment to gain access to a plant or warehouse or to intimidate or harass company officials or employees.*

If an inspector does resort to force or intimidating behavior to gain entry, the defendant in any subsequent criminal action may move to suppress any evidence obtained in the course of such inspection, and the motion will probably be granted.

WRITTEN NOTICE OF INSPECTION

2. *To obtain entry into a food plant an FDA inspector must present "appropriate credentials" and a "written notice" (Form FD-482) to the "owner, operator, or agent in charge."*

A separate notice must be given for each inspection, but a new notice is not necessary for each entry made during the period covered by a single inspection. The FDA inspection notice contains the date, time, name of inspector, address of the FDA district office and address of the plant. Most companies retain the notice as an official record of the inspection. The FDA inspector is obliged to seek out the most responsible person present at the facility, but even if a responsible official is not available the inspector is authorized to proceed with the inspection. Most companies deem it desirable to have the inspector accompanied by the plant manager or other responsible official, rather than to permit the inspector to wander through the facility on his own. Many companies designate an individual with primary responsibility for dealing with FDA inspectors and a backup person in the event that the person with primary responsibility is not available.

REASONABLENESS OF THE INSPECTION

3. *Inspections must be undertaken "at reasonable times and within reasonable limits and in a reasonable manner."*

In most instances a "reasonable time" would be interpreted to mean during the day and during ordinary business hours, except that inspections may be made at night or during holidays if the plant is in operation. The inspection should be commenced and completed with reasonable promptness. The term "reasonable limits" is interpreted to refer to the scope of the inspection, discussed below.

SCOPE OF INSPECTION

4. *The inspector is authorized to inspect any facility, warehouse or establishment in which foods are manufactured, processed, packed, or held for shipment into interstate commerce, or any vehicle used to transport foods in commerce, and to inspect "all pertinent equipment, finished and unfinished materials, containers, and labeling therein."*

The inspector has virtually unlimited authority to inspect the physical premises, to observe operations, and to examine finished and unfinished materials, containers and labeling. The interstate commerce limitation is no longer of any significance, since virtually every food processor ships at least some product in interstate commerce, or receives ingredients which have been shipped in interstate commerce.

COMPULSORY ACCESS TO RECORDS

5. *As a general rule FDA inspectors are not authorized to obtain compulsory access to company records.*

Other than the two exceptions listed below, FDA has no statutory authority to demand access to food establishment records. The legislative history of the 1953 amendments to Section 704 is somewhat ambiguous on this point, but both the language of the Act and consistent FDA interpretation support the view that a company may refuse access to its records and may not be prosecuted for such refusal. Records which the company may refuse to allow an inspector to review include personnel, formula, quality control and complaint files. As a matter of practice, however, FDA inspectors may be expected to request permission to see particular company records, and in all probability will not make it clear whether they have authority to insist on such access.

(a) *Under Section 703 of the Act, FDA does have a right of access to shipping documents relating to articles received in interstate commerce.*

This right of compulsory access to shipping records relates solely to articles *received* in interstate commerce by the establishment being inspected. FDA has no right to demand access to a processor's records of his own shipments. Even with respect to shipping documents relating to articles received

in commerce, the inspector must provide an appropriate written request. Companies should insist on the presentation of a written request in order to assure that such documents may not be used in a criminal prosecution against the operator. Courts have held that when a company has given an inspector access to shipping records in response to the inspector's oral request, those records may be used as evidence against the company.

(b) *Refusal of a processor to divulge low acid or acidified canned food processing records may result in the imposition of an emergency permit requirement on the company.*

Under Part 108 of the FDA regulations, processors of low acid and acidified canned foods are required to permit the inspection and copying by FDA of "any process and procedure information that FDA deems necessary to determine the adequacy of the process." Commercial processors of acidified and low acid canned foods are also required to prepare and retain at the processing plant or other reasonably accessible location for a period of 3 years from the date of manufacture all records of processing, deviations in processing and other records specified in Part 113 (low acid foods) and Part 114 (acidified foods). As with shipping records, FDA inspectors are required to present a written request to inspect acidified and low acid canned food records. Such records are ordinarily deemed trade secrets by FDA and are not disclosable to the public. Although failure to permit inspection of such records may not result in criminal prosecution, FDA is authorized to impose an emergency permit requirement on a company that refuses to allow inspection and copying of low acid or acidified food process records.

(c) *If company records are made available on a voluntary basis, FDA may use such records as evidence in criminal or civil proceedings against the company and its officials.*

A number of court decisions have made clear that if a company consents to an inspector's access to records, those records may be used as evidence in any appropriate enforcement action. Companies vary as to their policy with regard to permitting access to different categories of records. Because FDA can obtain shipping records from carriers, many companies permit FDA inspectors to examine their shipping records. Many food companies permit FDA inspectors to review their pesticide control records, or even some or all of their quality control records.

(d) *Company officials are not required to provide information in response to oral questions by the inspector, except as such questions may relate to the inspector's authorized inspection of the premises.*

In the course of inspection an FDA official may ask questions of company employees in an effort to obtain information about the company's operations. Employees are not required to answer such questions or to provide any information to the inspector. Employees should respond, however, to questions by the inspector relating to the authorized inspection of the facility, such as the location of particular goods or operations, and the like. Failure to respond completely or accurately to such questions may be interpreted as a refusal to permit inspection and may expose the company and the employee to prosecution.

PHOTOGRAPHS BY THE INSPECTOR

6. *The Act does not explicitly authorize FDA inspectors to take photographs in the course of food establishment inspections.*

FDA inspectors frequently attempt to take photographs during the course of a factory inspection. The FDA Inspection Operations Manual instructs inspectors routinely to take cameras into inspected establishments, to use them as necessary and not to seek permission from management before doing so. The question of an FDA inspector's right to use a camera during the course of inspection has not been authoritatively resolved by the courts, but many companies have refused to permit inspectors to take photographs. The FDA Inspection Operations Manual was recently revised to direct inspectors to inform the FDA district office when a company refuses to allow the inspector to take photographs, so that "legal remedies may be sought...if appropriate."

The FDA interprets a recent court decision as upholding FDA's right to take photographs over a company's objections. In Dow Chemical v. United States, 106 S. Ct. 1819 (1986), the Supreme Court ruled that the Environmental Protection Agency (EPA) has inherent authority under the Clean Air Act to take photographs of inspected facilities. Although the Dow decision is interpreted by FDA as supporting its claim for compulsory photograph authority, there are legitimate grounds for distinguishing FDA inspections. The legislative history of the FD&C Act indicates that Congress intended to circumscribe FDA's inspection power, and the Dow decision involved photographs of areas open to public view rather than in-

plant premises. The applicability of the Dow decision to FDA photographs of food plants ultimately will have to be resolved by the courts.

(a) *If an inspector takes photographs without objection by the company, the photographs may be used as evidence in an appropriate enforcement proceeding.*

If photographs are taken over the objections of the company, it is possible that a court might suppress the use of such photographs in any enforcement proceeding, depending upon the court's determination of FDA's photograph authority.

(b) *Many companies insist that FDA inspectors leave their cameras at the factory door.*

The revised FDA Inspection Operations Manual indicates that FDA may become more aggressive in seeking in-plant photographs. Nevertheless, there has been no definitive test of FDA photograph authority, and many food plants continue to refuse to permit photographs. The most likely test of FDA photograph authority would arise in the context of an FDA effort to obtain a warrant to require an uncooperative firm to permit photography. If FDA makes application for a warrant to require photographs, the inspected firm may oppose the warrant on the grounds that photos are not authorized under the statute or not justified in the particular case, or may seek a protective order limiting the circumstances under which FDA can take or use photos containing trade secrets or confidential material. Where FDA obtains a warrant specifically authorizing photography, a further refusal to permit photography could result in personal and corporate penalties for contempt of court.

(c) *Firms that permit FDA to take in-plant photographs can take prudent steps to protect against the disclosure of trade secrets and to minimize the use by FDA of inaccurate or misleading photos.*

Where a firm permits FDA to take photographs of its facilities, the photographs may be disclosed to the public under the Freedom of Information Act subject to trade secret protections. Management should request that FDA exclude trade secrets from in-plant photographs whenever possible. If an FDA photo includes trade secrets or commercially sensitive areas, management should request that the photo and any negative be marked as confidential, and should confirm this by letter to FDA. To counteract misleading or inaccurate FDA photographs, an inspected firm should take and retain its own photos of the same and adjoining areas photographed by FDA.

RECORDINGS

7. *FDA is not authorized to tape record discussions with plant management during a food plant inspection.*

The Act and FDA regulations do not explicitly authorize use of tape recordings by FDA inspectors. Following Congressional hearings in 1965 regarding FDA inspectors' use of tape recorders and other electronic surveillance equipment, FDA adopted a policy against use of tape recordings during inspections. However, the FDA Inspection Operations Manual provides that where plant management chooses to tape record discussions with an FDA inspector, the inspector will seek to record the conversation as well.

WRITTEN REPORT OF INSPECTION

8. *Upon completion of an inspection and prior to leaving the premises the FDA inspector is required to give the owner, operator, or agent in charge a written report "setting forth any conditions or practices... which... indicate that any food... in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substances, or (2) has been prepared, packed, or held under insanitary conditions... ."*

(a) *Written inspection reports are ordinarily available to the public under the Freedom of Information Act.*

A copy of the inspector's written report (Form FD-483) must also be sent promptly to FDA. Under current practice, FDA inspectors also complete an Establishment Inspection Report (EIR) which contains the inspector's conclusions and recommendations to his superiors. This report is not ordinarily submitted to the processor, but may be requested under the Freedom of Information Act. The contents of FD-483s and EIRs will ordinarily be made available to the public under the Freedom of Information Act, except that FDA withholds disclosure of enforcement recommendations in EIRs during active investigations. Information contained in FD-483s will be made available to the public immediately except in the rare instance where a factory inspection report contains a trade secret.

(b) *Management should respond promptly and completely to FDA written observations of violative conditions.*

In addition to providing a report of adverse findings to plant

management (FD-483), most FDA district offices send a letter to senior management listing the same adverse findings. Management should respond to such letters, as well as the FD-483, promptly and in detail, specifying areas of disagreement and the grounds thereof, and explaining specific steps taken to assure compliance.

RECEIPTS FOR SAMPLES AND COPIES OF ANALYSES

9(a) *If an FDA inspector takes any sample in the course of an inspection he must give the owner, operator, or agent in charge, prior to leaving the premises, a receipt describing the sample obtained. (Form FD-484).*

In collecting samples, the inspector is required to follow procedures designed to insure that the samples accurately represent the lot being sampled and that the act of sampling does not contaminate either the sample or the lot. FDA practice is to pay a fair price (processor's invoice cost plus 10 percent for handling) for any significant samples taken in the course of an inspection. Sampling procedures and the size of the sample will vary depending upon the purpose of the inspection and nature of the material being sampled.

(b) *Food companies should instruct their employees to obtain equivalent company samples at the same time and under the same circumstances as samples taken by FDA.*

(c) *The Act requires FDA promptly to furnish to the company a copy of the results of any analysis made of samples taken in the course of an inspection and indicating whether such foods are unfit for consumption.*

IN GENERAL

Because of the severe sanctions available for violation of any provision of the Federal Food, Drug, and Cosmetic Act, an FDA inspection of a food plant or warehouse must be regarded as of vital importance to the company and its employees. Responsible company officials should be thoroughly familiar with both the requirements of the Act and company policy with respect to such inspections so that the inspector's visit can be handled on an orderly

and routine basis. The company official accompanying the inspector through the facility should take notes of comments, questions or suggestions made by the inspector. Immediately after the inspector has departed the official should prepare a full report of the inspection for company management.

Although it is entirely reasonable for companies to insist that the inspection be restricted to the limits of FDA's statutory authority, an effort should be made by company employees to cooperate with the inspector within those limits, and the inspection should not be regarded as an adversary or unfriendly proceeding. The industry must recognize the obligations of FDA to administer and enforce the FD&C Act according to its terms and in the public interest, and there can be no doubt that the FDA, industry, and consumers share a common interest in the integrity and wholesomeness of the food supply.

In short, an FDA inspection should be handled seriously and cooperatively, in strict accordance with established company policy.

Annotation

Freedom of Information Act

The FDA Freedom of Information Act regulations can be found at 21 C.F.R. part 20; the trade secret exemption is § 20.61.

For FOIA cases, see Campbell v. Health and Human Services, 682 F.2d 256 (D.C. Cir. 1982) (exemption from FOIA for investigatory records of a pending enforcement proceeding); Carson Products Co. v. Califano, 594 F.2d 453 (5th Cir. 1979) (upholding FDA procedures for evaluating requested trade secret exemptions from FOIA).

In addition to the cases, see Fortunato, FDA Disclosure of Safety and Efficacy Data: The Scope of Section 301(j); 52 Fordham L. Rev. 1280 (1984) (discussion of application of the FOIA trade secret exemption to data submitted to FDA); Olsson, Food Inspection: The Quest for Objectivity, 35 Food Drug Cosm. L.J. 149 (1980) (description of regulations governing the trade secret exemption to the FOIA); Jackson, FDA Inspectional Records and Freedom of Information, 33 Food Drug Cosm. L.J. 692 (1978) (discussion of FOIA regulations as applied to records of factory inspections).

General

See FDA Inspection Operations Manual § 501 (inspection authority); Merrill and Hutt, *Food and Drug Law Cases and Materials* 703-720 (1980); Hansen, An FDA Inspection: Preparing for the Inevitable, 36 Food Drug Cosm. L.J. 641 (1981) (discussion of need for company policy and program to ensure that managers are aware of policy); Schaeffer, Inspection Policy, 36 Food Drug Cosm. L.J. 493 (1981) (discussion of need for and scope of company inspection policy); Lushbough, A Food Company's Approach to the Inspectional Process, 35 Food Drug Cosm. L.J. 436 (1980) (discussion of company's policies and procedures); Shupack, The Inspectional Process: A Statutory Overview, 33 Food Drug Cosm. L.J. 697 (1978) (discussion of historical development and extent of FDA inspection authority).

Harassment

See Southeastern Minerals, Inc. v. Harris, 622 F.2d 758 (5th Cir. 1980) (court may enjoin inspections that are "unduly threatening, harassing"). See also FDA Inspection Operations Manual § 510 (procedures for inspector responses to hostile plant personnel).

Inspection Reports

See FDA Inspection Operations Manual § 512 (FD-483), § 516 (end-of-inspection discussion); McNamara, The FDA Inspection: What You Need to Know to Protect Your Company, 36 Food Drug Cosm. L.J. 245 (1981) (description of end-of-inspection discussion and inspection reports and the need for companies to respond to inspection reports); Celeste, The Inevitable FDA Inspection, 34 Food Drug Cosm. L.J. 32 (1979) (discussion of purpose and nature of various inspection reports); Swanson, How to Handle an FDA Inspection—The Investigator's View, 33 Food Drug Cosm. L.J. 109 (1978) (description of purpose of and problems encountered in inspector's end-of-inspection discussion).

Notice of Inspection

See FDA Inspection Operations Manual § 501.1 (notice required), § 511 (procedures); Feinberg, FDA Investigator: "From His Office to Yours," 36 Food Drug Cosm. L.J. 486 (1981) (discussion of FDA notice procedures).

Oral Questions

See United States v. Diaz, 690 F.2d 1352 (11th Cir. 1982) (may decline to answer but not knowingly lie).

Photographs

For additional cases addressing in-plant photographs by FDA, see Durovic v. Palmer *et al.*, 342 F.2d 634 (7th Cir. 1965) (in absence of evidence on intended use, court declined to rule on legality of photographs); United States v. Gel Spice Co., Inc., 601 F. Supp. 1214 (E.D. N.Y. 1984) (photographs admissible evidence); United States v. Acri Wholesale Grocery Co., 409 F. Supp. 529 (S.D. Iowa, 1976) (photographs taken without objection during valid inspection admissible evidence of violation of FD&C Act).

For a discussion of in-plant photographs, see FDA Inspection Operations Manual § 523 (inspectors directed to take photographs); Basile, The Case Law on Inspections, 34 Food Drug Cosm. L.J. 20 (1979) (discussion of FDA's reasons for asserting that FDA's inspection authority encompasses the right to take photographs).

Reasonableness

See United States v. New England Grocers Supply Co., 488 F. Supp. 230 (D.C. Mass. 1980) (inspection over 5 days is reasonable).

Records

See *In Re* Establishment Inspection Portex, Inc., 595 F.2d 84 (1st Cir. 1979) (FDA record inspection authority encompasses records and products described in § 704 of the FD&C Act); United States v. Stanack Sales Co., 387 F.2d 849 (3rd Cir. 1968) (FDA inspection authority does not extend to business records); *In Re* Medtronics, Inc., 500 F. Supp. 536 (D. Minn. 1980) (FDA inspection authority does not encompass complaint files).

See also FDA Inspection Operations Manual § 501.1 (authority), § 527 (FDA handling of copies of records), § 530.32 (low acid and acidified canned foods); McNamara, The FDA Inspection: What You Need to Know to Protect Your Company, 36 Food Drug Cosm. L.J. 245 (1981) (discussion of FDA procedures used to gain access to records); Doherty, The Inspection Process, 35 Food Drug Cosm. L.J. 535 (1980) (discussion of one company's policy concerning access to records); O'Keefe, Legal Issues in Food Establishment Inspections, 33 Food Drug Cosm. L.J. 121 (1978) (discussion of FDA authority to inspect a variety of records); McKray, Record Inspection 1906-1963, 18 Food Drug Cosm. L.J. 301 (1963) (discussion of history of FDA inspection of business records).

Refusal to permit entry

For cases concerning the consequences of a refusal to permit entry, see United States v. Jamieson-McKames Pharmaceuticals, Inc., 651 F.2d 532 (8th Cir. 1981) (refusal to permit warrantless inspection is criminal offense), *cert. denied*, 455 U.S. 1016 (1982); United States v. Roux Laboratories, Inc., 456 F. Supp. 973 (M.D. Fla. 1978) (civil contempt for refusal to comply with search warrant).

In addition to cases, see FDA Inspection Operations Manual §§ 514–15 (responses to refusal to permit entry); Safir, Establishment Inspections: The Risk of Refusal, 33 Food Drug Cosm. L.J. 680 (1978) (discussion of issues a company should consider in determining whether to refuse entry to an inspector).

Samples

See FDA Inspection Operations Manual chptr. 4 (sampling), chptr. 5 § 513 (receipts), § 521 (purpose); DeBell & Chesney, The FDA Inspection Process, 37 Food Drug Cosm. L.J. 244 (1982) (discussion of purposes for FDA sampling); Feinberg, FDA Investigator: "From His Office to Yours," 36 Food Drug Cosm. L.J. 486 (1981) (description of FD-484, Receipt for Samples).

Scope

See DeBell & Chesney, The FDA Inspections Process, 37 Food Drug Cosm. L.J. 244 (1982) (discussion of scope of inspection authority).

Search warrant

For cases concerning warrantless inspections, see Marshall v. Barlow's, Inc., 436 U.S. 307 (1978) (consent or warrant required for OSHA inspection); United States v. Biswell, 406 U.S. 311 (1972) (warrant not necessary for inspection of premises of federally licensed gun dealer); Colonnade Catering Corp. v. United States, 397 U.S. 72 (1970) (warrant not necessary for inspection in heavily regulated liquor industry); United States v. Gel Spice Co., Inc., 773 F.2d 427 (2nd Cir. 1985) (FDA may conduct routine inspection during pendency of decision concerning criminal prosecution based on prior inspection), *cert. denied*, 106 S. Ct. 804 (1986); United States v. New England Grocers Supply Co., 488 F. Supp. 230 (D.C. Mass. 1980) (neither warrant nor consent required for inspection of food in interstate commerce); United States v. Del Campo Baking Manufacturing Co., 345 F. Supp. 1371 (D.C. Del. 1972) (FD&C Act authorizes warrantless search).

In addition to cases, see O'Reilly, Bad Actors Make Worse Law: Expansion of the Narrow Constitutional Exception for Warrantless Searches, 37 Food Drug Cosm. L.J. 368 (1982) (discussion of the expansion of FDA's warrantless search authority); Norton, The Constitutionality of Warrantless Inspection by the Food and Drug Administration, 35 Food Drug Cosm. L.J. 25 (1980) (discussion of the application of *Marshall* to the FDA); Allera, Warrantless Inspections of the Food Industry, 34 Food Drug Cosm. L.J. 260 (1979) (discussion of how cases authorizing warrantless inspection in regulated industries apply to the food industry).

For cases concerning FDA's power to obtain a search warrant, see United States v. Storage Spaces Designated Nos. 8 & 49, 777 F.2d 1363 (9th Cir. 1985) (discussion of evidence of possible violation of FD&C Act necessary to support search warrant), *cert. denied*, 107 S. Ct. 1291 (1987).

Tape Recorders

See FDA Inspection Operations Manual § 524 (procedures to tape inspections and end-of-inspection discussions); "Invasions of Privacy (Government Agencies)," Hearings on S. Res. 39 Before the Subcomm. on Administrative Practice and Procedure of the Senate Comm. on the Judiciary, Part 2, 89th Cong., 1st Sess. (1965).

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