

## **Attachment II**

### **FDA RECORDS INSPECTION AUTHORITY**

FDA has no statutory authority under the Federal Food, Drug, and Cosmetic Act (FDCA) to *require* companies to allow agency inspection of food company records except under very limited circumstances. FDA itself has maintained this position over many years, and has articulated this view before Congress in numerous instances where the agency sought such authority. In the absence of congressionally-delegated records inspection authority, FDA may not create such authority for itself through the vehicle of GMP regulations, even to ensure compliance with regulations the agency is authorized to mandate.

#### **FDA Has No Statutory Authority to Inspect Records Other Than in a Few Limited Instances**

Section 704(a) of the FDCA provides that FDA's authority to inspect the factory, warehouse, establishment, or vehicle of a food manufacturer or processor is limited to "all pertinent equipment, finished and unfinished materials, containers, and labeling therein." By its plain language, the statute does not extend this authority to the inspection of the records of such food facilities. By contrast, section 704(a) expressly provides for records inspection for prescription drugs, specified medical devices, infant formula, and human nonprescription drugs. Under ordinary principles of statutory interpretation, the expression of one thing is the exclusion of another. It is therefore clear that Congress intended to allow records inspection authority only in the limited and enumerated fields, and meant to withhold such authority for inspection of food facilities.

Moreover, the provisions in section 704(a) allowing records inspection in certain arenas were added by amendments to the FDCA subsequent to its initial enactment. If the general provision quoted above regarding the scope of inspections was intended to encompass records inspection, no such amendments would have been required, and the resulting provisions would be superfluous.

Further, FDA may not create records inspection authority by regulation under section 701(a) of the FDCA. That section grants FDA the authority to promulgate regulations for the efficient enforcement of the Act. However, the provision authorizes FDA to issue only regulations implementing other substantive provisions of the Act. It does not permit the agency to impose regulatory requirements that exceed the limited congressionally-delegated inspection authority provided under the statute. See *National Confectioners Association v. Califano*, 569 F.2d 690, 695 (D.C. Cir. 1978) ("the regulation must be consistent with Congressional intent and the substantive provisions of the whole statute. Section 701(a) is not a license for expansion of

the FDA's regulatory authority based on fanciful interpretations of the substantive portions of the Act.”).

NFPA recognizes, and does not object to, the fact that FDA has established records inspection authority for acidified and low-acid canned foods in 21 C.F.R. §§ 108.25(g) and 108.35(h). However, these regulations were promulgated under FDA's emergency permit control authority set forth in Section 404 of the FDCA. Section 404(c) grants FDA access to any facility whose operator holds such an emergency permit, for the purpose of ascertaining whether the conditions of the permit are being met. This authority does not extend beyond the context of emergency permits, and cannot be analogized to general GMP inspections. To the contrary, the fact that Congress established this inspection authority in the specific context of emergency permits further demonstrates that such authority is not allowed under the broader provisions of Section 704(a).

The FDCA grants FDA the authority to inspect food company records in a few other limited circumstances that are not applicable to the GMP context. Section 703 allows FDA to inspect records that document the interstate shipment of food. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 added Section 414(a), which authorizes food records inspection where FDA has “a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death,” and Section 801(d)(3)(A)(iv), authorizing records inspection relating to “import for export.” Again, these limited, specific grants of records inspection authority further demonstrate that FDA is not authorized to inspect records of food companies in other contexts.

### **FDA Has Long Acknowledged that It Lacks Authority to Inspect Food Records**

For over fifty years, FDA has acknowledged that it lacks authority to inspect the records of food facilities, and has repeatedly but unsuccessfully sought such authority from Congress. Congress enacted the limited factory inspection provision at Section 704 in 1953, despite the fact that FDA had sought statutory authority to inspect all relevant records relating to food production. On August 27, 1953, FDA issued a press release expressly acknowledging its lack of mandatory records inspection authority, quoting FDA Commissioner Charles Crawford as stating:

The legislative history indicates Congress did not intend to include prescription files, formula files, complaint files, and personnel files within the scope of required inspections. FDA interprets this to mean that inspection of these records will be on a voluntary basis.

Most recently, the 2004 FDA *Investigations Operations Manual* expressed the same agency understanding of its authority as set forth in 1953:

Limitations -- Section 704 of the FD&C Act [21 U.S.C. 374] provides authority for FDA to conduct inspections . . . This section does not include a provision to inspect records within those

facilities, except for inspections of prescription drugs, nonprescription drugs intended for human use, and restricted devices . . . or inspections of infant formula . . . .

FDA, *Investigations Operations Manual* Section 701.01 (2004). On occasions between 1953 and 2004 too numerous to detail in these comments, FDA has articulated this understanding of its limited authority to inspect records. In many instances, this acknowledgement was presented to Congress in seeking records inspection authority for food facilities, but Congress has continually refused to grant such authority.

Notably, FDA has on a number of occasions addressed its lack of authority to inspect food records relating to GMP-type activities. During the 1971 hearings before the Subcommittee on Public Health and Environment of the House Committee on Interstate and Foreign Commerce relating to FDA oversight/food inspection, the agency again sought expansion of its existing food inspection authority from Congress. FDA Commissioner Charles Edwards and Virgil Wodicka, Director of the FDA Bureau of Foods, asserted that the agency's ability to monitor the quality control systems of food manufacturers was impaired because it lacked the authority to inspect records. In his testimony, Dr. Wodicka expressly acknowledged that Congress had repeatedly denied FDA the authority to inspect food records:

DR. WODICKA: Our inspection efforts have been almost entirely concentrated on the inspection of the plant and the operations in it, and have paid somewhat less attention to the controls of those operations exercised by the company.

This is in part because the agency has a number of times asked for authority to require the companies to show quality control records and the Congress has never felt that this was a necessary authority.

As a consequence, we are able to look at these records only from those companies that will voluntarily show them.

I think the number of such companies is increasing, and we want to mount a training program to put our inspectors in a position to make more effective use of this kind of information when it is available.

"FDA Oversight - - Food Inspection," *Hearings before the Subcommittee on Public Health and Environment of the Committee on Interstate and Foreign Commerce, House of Representatives*, 92nd Cong., 1st Sess. 130-131 (1971).

Similarly, during the Senate's consideration of the Consumer Food Act of 1975, FDA Commissioner Schmidt submitted a prepared statement that explained:

It is essential that FDA possess sufficient authority to determine the manner in which food is being processed. Although FDA's

primary source of information in this regard is the factory inspection, present authority to inspect food processors is severely limited. An FDA inspector under our current law is limited to a visual examination of the processing in a particular establishment. He is not entitled to inspect records showing the source of materials, quality controls, or formulation of the products.

“Food Safety and Labeling Legislation,” *Joint Hearings before the Subcommittee for Consumers of the Committee of Commerce and the Subcommittee on Health of the Committee on Labor and Public Welfare, United States Senate, 94th Cong., 1st Sess. 85 (1975)*. Although the Senate Report on the legislation emphasized that it would “enable FDA to require maintenance of and access to records” (S. Rep. No. 94-684, 94th Cong., 2d Sess. 6 (1976)), the legislation was not enacted.

Again in 1991, during hearings on the Food, Drug, Cosmetic, and Device Enforcement Amendments, FDA acknowledged its lack of records inspection authority when Commissioner Kessler answered in response to a written question that the FDCA “does not authorize FDA access to safety testing data.” “Role of Commissioner of Food and Drugs,” *Hearing before the Committee on Labor and Human Resources, United States Senate, 102nd Cong., 1st Sess. 122 (1991)*. The following week, he testified before the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce and again referred to the need for “adequate tools such as records inspection” and said that “the statute in the food area does not have records inspection.” “Food and Drug Administration Oversight,” *Hearings before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, House of Representatives, 102d Cong., 1st Sess. 7, 22 (1991)*.

Accordingly, FDA has expressed its understanding consistently and publicly over the past fifty years that it does not have authority to inspect the records of food facilities, even in order to determine compliance with safety and quality controls. Under well-settled principles of administrative law, the agency’s longstanding interpretation of a provision of the FDCA is presumed correct. *See, e.g., Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944) (weight given to rulings, interpretations and opinions of an agency depends upon “the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade”). FDA bears a heavy burden to justify the reversal of this longstanding position. *See, e.g., E.g., Motor Vehicle Manufacturers Association v. State Farm Mutual Insurance*, 463 U.S. 29, 48-49 (1983) (when departing from a settled policy, an agency must explain both the basis for its decision and the basis for reversing its previous policy); *General Electric Co. v. Gilbert*, 429 U.S. 125, 142-43 (1976) (assigning little weight to an agency’s statutory interpretation which “flatly contradict[ed]” the position previously articulated by the agency); *Madison Galleries, Ltd. v. United States*, 870 F.2d 627, 631 (Fed. Cir. 1989) (“an agency interpretation which conflicts with the same agency’s earlier interpretation is entitled to considerably less deference than a consistently held agency view”), citing *INS v. Cardoza-Fonseca*, 480 U.S. 421, 447 n. 30 (1987).

**Congress' Refusal to Grant FDA Inspection Authority for Food Records Reflects a Determination that Such Authority is Unnecessary for the Effective Enforcement of the FDCA**

In each of the many instances in which Congress considered expanding FDA's inspection authority to allow mandatory records inspection for food facilities, both FDA and food industry representatives presented their views before Congress. Accordingly, Congress' determination not to grant such inspection authority has been an informed one. Further, Congress has undoubtedly been mindful of the constitutional and other serious issues involved in allowing FDA inspectors to review food company records without a search warrant and without a showing of probable cause to believe there has been a violation of law. Unlike most government investigators, FDA inspectors may gain entry to food establishments without a warrant and with no advance notice or special permission from the owner or operator, and refusal to permit an FDA inspection is a criminal offense. Moreover, Congress has observed that allowing FDA access to food records could compromise the trade secrets of industry members. *See* exchange between Congressman Hastert and Commissioner Kessler during the 1991 Hearings on the Food, Drug, Cosmetic, and Device Enforcement Amendments. H.R. 2597, "Food, Drug, Cosmetic, and Device Enforcement Amendments," *Hearing before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, House of Representatives*, 102nd Cong., 1st Sess. 87 (1991).

Further, FDA itself has asserted that it is competent to administer the FDCA even without authority to inspect food records. For example, FDA Deputy Commissioner for Policy Michael Taylor testified before the Senate Committee on Labor and Human Resources on pending new enforcement legislation in May 1992 that "[o]ur enforcement record illustrates the general ability to accomplish enforcement objectives utilizing current statutory and regulatory authorities. . . . The administration continues to believe that increased enforcement authorities are not necessary to protect the public health or safety. Existing authorities are sufficient to accomplish the intent of the food and drug act and related statutes." "Food, Drug, Cosmetic, and Device Enforcement Authorities Act," *Hearing of the Committee on Labor and Human Resources, United States Senate*, 102d Cong., 2d Sess. 6-7 (1992).

Finally, FDA has acknowledged that food manufacturers routinely provide records to FDA inspectors upon reasonable request. For this reason and those mentioned above, Congress has determined not to extend FDA's already expansive powers to include inspection authority for food records.

Potential revision of the food GMPs present no novel issues that have not been previously presented before Congress. It is therefore clear that Congress has considered and rejected any arguments that might be asserted to support records inspection authority in the context of food GMPs. Without such statutory authorization, FDA may not assert mandatory records inspection authority, even through regulation. NFPA members intend to continue their historical cooperation with the agency with respect to voluntary records access.