Contains Nonbinding Recommendations

Guidance for Industry

FDA Records Access Authority Under Sections 414 and 704 of the Federal Food, Drug, and Cosmetic Act

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U.S. Department of Health and Human Services
Food and Drug Administration
Office of Foods and Veterinary Medicine
Center for Food Safety and Applied Nutrition
Center for Veterinary Medicine
Office of Regulatory Affairs

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Table of Contents

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I. Introduction

This guidance document provides updated information pertaining to the Food and Drug Administration's (FDA) authority to access and copy records under sections 414 and 704 of the Federal Food, Drug, and Cosmetic Act (FD&C Act). This guidance is a revision of FDA's November 2005 guidance entitled "Guidance for Industry and FDA Staff: Guidance for records access Authority Provided in Title III, Subtitle A, of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Final Guidance." FDA's staff manuals, the Regulatory Procedures Manual (RPM) and Investigations Operations Manual (IOM), contain operational and procedural steps for FDA staff to follow for accessing records under sections 414 and 704 of the FD&C Act; therefore, that information has been removed from this guidance. Both the RPM and IOM are located on FDA's website, www.fda.gov.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Background

The FDA Food Safety Modernization Act (FSMA) (Public Law 111-353) was signed into law on January 4, 2011. Section 101 of FSMA amends section 414(a) and 704(a)(1)(B) of the FD&C Act (21 U.S.C. 350c(a) and 374(a)(1)(B)). Section 414 was originally added to the FD&C Act by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the

[1] This guidance has been prepared by the Office of Compliance in the Center for Food Safety and Applied Nutrition in cooperation with the Center for Veterinary Medicine at the U.S. Food and Drug Administration.

Bioterrorism Act) (Public Law 107-188). Prior to the passage of FSMA, section 414(a) of the FD&C Act provided the Secretary (by delegation FDA) with access to records relating to food that was reasonably believed to be adulterated and present a threat of serious adverse health consequences or death to humans or animals. FSMA expands FDA's access to records beyond records relating to the specific suspect article of food to records relating to any other article of food that the FDA reasonably believes is likely to be affected in a similar manner. In addition, FDA can now access records if FDA believes that there is a reasonable probability that the use of or exposure to an article of food, and any other article of food that FDA reasonably believes is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animals. The Bioterrorism Act also amended section 704(a)(1)(B) of the FD&C Act to include a cross-reference to section 414. Section 101 of FSMA amends this section, which pertains to factory inspections, by updating the cross-reference to refer to the amended version of section 414(a).

FDA's access to records under section 414 is separate from previously existing routine records access provided in commodity specific regulations, such as the Low-Acid Canned Food regulations (21 CFR part 113), the Acidified Food regulations (21 CFR part 114), the Juice Hazard Analysis and Critical Control Point (HACCP) Systems regulations (21 CFR part 120), the Fish and Fishery Products regulations (21 CFR part 123), and the Infant Formula regulations (21 CFR part 106). These commodity specific record access regulations were not amended by FSMA.

III. Questions and Answers

1. Does FDA's records access authority under sections 414(a) and 704(a) of the FD&C Act apply to records relating to human food and/or animal food?

Yes. The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article, as defined in section 201(f) of the FD&C Act (21 U.S.C. 321(f)).

2. Does FDA's records access authority under sections 414(a) and 704(a) apply to both domestic and foreign persons?

Yes. FDA's records access authority under sections 414(a) and 704(a) applies to both domestic and foreign persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import articles of food when the circumstances in section 414(a)(1) or (2) of the FD&C Act are met. A person's refusal to permit FDA to access and copy any record as required by section 414(a) or 704(a) is a prohibited act under section 301(e) of the FD&C Act (21 U.S.C. 331(e)). The term "person" has the same meaning as defined in section 201(e) of the FD&C Act to include individual, partnership, corporation, and association.

FDA prefers that requested records relating to the manufacture, processing, packing, transportation, distribution, receipt, holding or importation of food that is intended for or enters the U.S. supply chain to be provided to the Agency in English.

3(a). Under what circumstances may FDA access and copy records under section 414(a) of the FD&C Act?

FDA may access and copy records from domestic and foreign persons who manufacture, process, pack, transport, distribute, receive, hold, or import food (excluding farms and restaurants) if:

- (1) FDA has a reasonable belief that the food, and any other food that FDA reasonably believes is likely to be affected in a similar manner,
    a) is adulterated, and
    b) presents a threat of serious adverse health consequences or death to humans or animals.
- Or, (2) FDA believes that there is a reasonable probability that use of or exposure to the food, and any other food that the FDA reasonably believes is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animals.

3(b). What records may FDA access and copy if the circumstances under section 414(a) of the FD&C Act are met?

- If the circumstances in (1) are met, FDA may access and copy the records that are needed to assist FDA in determining whether the food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals
- If the circumstances in (2) are met, FDA may access and copy the records that are needed to assist FDA in determining whether there is a reasonable probability that the use of or exposure to the food will cause serious adverse health consequences or death to human or animals.

4. When is FDA likely to exercise its authority under section 414(a) and 704(a) of the FD&C Act to access and copy records?

FDA may request to access and copy records whenever the requirements of section 414(a)(1) or (2) are satisfied, but requests are most likely to occur when FDA becomes aware of:

- Reportable food reports, as defined in section 417(a)(2) of the FD&C Act [21 U.S.C. 350f(a)(2)]
- Foodborne outbreaks
- Epidemiological evidence which implicates food causing illness or death
- Product recalls
- Adverse event reports
- Consumer complaints

- Situations in which specific foods (or other foods that are reasonably likely to be affected in a similar manner) present a threat of serious adverse health consequences or death to humans or animals

5(a). What are some examples of situations in which food may cause serious adverse health consequences or death to humans or animals?

The following are some examples of situations in which food may cause serious adverse health consequences or death to humans or animals:

- Peanut butter contaminated with *Salmonella*
- Under-processed canned chili that contains *Clostridium botulinum* toxin
- Smoked salmon contaminated with *Listeria monocytogenes*
- Cake mix that contains milk that is not declared in the ingredient statement on the label
- Candy contaminated with peanuts because of cross-contact with another food that contained peanuts as an ingredient
- Baby food that poses a choking hazard
- Horse feed contaminated with elevated levels of monensin
- Pet food contaminated with elevated levels of melamine and cyanuric acid
- Sheep feed that contains elevated levels of copper
- Swine feed that contains elevated levels of selenium

5(b). What are some examples of situations in which food is "likely to be affected in a similar manner" and may cause serious adverse health consequences or death to humans or animals?

The following are some examples of situations in which food can be considered "likely to be affected in a similar manner" and may cause serious adverse health consequences or death to humans or animals:

- *Salmonella* outbreak in which, based on epidemiological data, multiple foods are initially implicated as potential sources of the *Salmonella*
- Articles of food prepared or packed on an identical processing line as another article of food which may cause serious adverse health consequences or death to humans or animals
- Articles of food that are processed in shared-use equipment and that equipment was used to process an article of food which may cause serious adverse health consequences or death to humans or animals
- Articles of food that were prepared, packed or held under similar conditions as an article of food which may cause serious adverse health consequences or death to humans or animals

6. What records may FDA access and copy under sections 414(a) and 704(a) of the FD&C Act?

FDA's authority under sections 414(a) and 704(a) of the FD&C Act applies to records that are required to be kept by regulation under section 414(b), as well as any other records related to the manufacture, processing, packing, transporting, distribution, receipt, holding, or importation of the food believed to be affected and any other article of food believed to be affected in a similar manner. This applies to records maintained by or on behalf of such person, in any format (including paper and electronic formats), and at any location. FDA recognizes that some persons store their records at a location other than the facility where the covered activities take place. Because the circumstances of each particular event vary, the scope of an FDA request for records may vary in each situation.

Examples of records that FDA can access and copy include:

- Manufacturing records
- Raw materials (ingredients and packaging) receipt records
- Product distribution records
- Product inventory records
- Test records
- Recall records
- Reportable food records
- Customer distribution lists
- Complaint and adverse event records

7. What records may FDA not access and copy under sections 414(a) and 704(a) of the FD&C Act?

FDA's authority to access records under sections 414(a) and 704(a) of the FD&C Act does not apply to the following records:

- Records from farms, as defined in 21 CFR 1.328 – *Farm* means a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. Washing, trimming of outer leaves, and cooling produce are considered part of harvesting. The term "farm" includes:

    1. Facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership: and

    2. Facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership.

- Records from restaurants, as defined in 21 CFR 1.328 – *Restaurant* means a facility that prepares and sells food directly to consumers for immediate consumption. "Restaurant"

does not include facilities that provide food to interstate conveyances, central kitchens, and other similar facilities that do not prepare and serve food directly to consumers. Facilities in which food is directly provided to humans, such as cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens, and nursing home kitchens, are restaurants. Pet shelters, kennels, and veterinary facilities in which food is directly provided to animals are restaurants.

- Records relating to food that is within the exclusive jurisdiction of the Secretary of Agriculture pursuant to the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031 et seq.)
- Recipes, as defined in 21 CFR 1.328 - A "recipe" is the formula, including ingredients, quantities, and instructions necessary to manufacture a food. Because a recipe must have all three elements, a list of the ingredients used to manufacture a food, without quantity information and manufacturing instructions, is not a recipe.
- Financial data
- Pricing data
- Personnel data
- Research data
- Sales data other than shipment data regarding sales

8. What actions may FDA take when a firm refuses to permit access to records?

The refusal to permit access to or copying of records requested under section 414(a) of the FD&C Act is a prohibited act under section 301(e) of the FD&C Act [21 U.S.C. 331(e)]. In response to such a refusal, FDA may initiate civil or criminal action, as necessary. In addition, FDA may refuse admission of food offered for import into U.S. commerce by a firm that refused to permit FDA to access records.

Depending on the situation, FDA may initiate additional administrative, judicial, or other action, as appropriate, in conjunction with a records access request. These additional actions are distinct from a records access request and the existence of a records access request does not alter the process or timeframes established for these additional actions. Moreover, refusal to permit FDA access to records is not a prerequisite for using these additional actions. Such additional actions may include:

- Suspension of the food facility's registration, thus preventing the firm from importing or exporting food or introducing food into interstate or intrastate commerce
- Administrative detention of the food to control its movement
- Seizure of the food
- Issuance of a mandatory recall order for the food
- Injunction against the firm

9. How will FDA maintain the confidentiality of any protected information in records it obtains?

Information obtained under the records access provisions of sections 414(a) and 704(a) of the FD&C Act may include, but is not limited to, a company's non-public confidential commercial or trade secret information. Several statutes (e.g., Trade Secrets Act (18 U.S.C. 1905), FD&C Act (21 U.S.C. 331(j)), the Freedom of Information Act, (5 U.S.C. 552) and the agency's information disclosure regulations at 21 CFR Parts 20 and 21 govern the agency's disclosure of information to the public. For both foreign and domestic firms, FDA personnel will comply with all applicable protections, procedures, and legal requirements against the unauthorized disclosure of non-public information, such as any trade secret or confidential commercial information. FDA personnel may disclose non-public information otherwise protected from disclosure to the public, if that disclosure is permitted by law and FDA's procedures (see e.g. 21 U.S.C. 375(b)). For example, FDA's regulations (set forth in 21 CFR Parts 20 and 21) permit agency officials to disclose certain non-public information to other federal, state, local, or foreign government officials, or to FDA's contractors, when that disclosure is carried out according to law and FDA's procedures.