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Guidance for Industry

What You Need To Know About Establishment, Maintenance, and Availability of Records Small Entity Compliance Guide

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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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Guidance for Industry¹

What You Need To Know About Establishment and Maintenance of Records

Small Entity Compliance Guide

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

I. Introduction

On February 23, 2012, the Food and Drug Administration (FDA) published an interim final rule (IFR) in the Federal Register (77 FR 10658) that amended its regulation on the availability of records to be consistent with the amendments to section 414(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) made by section 101 of the FDA Food Safety Modernization Act (FSMA) (Public Law 111-353). The IFR became effective on March 1, 2012. April 4, 2014, FDA issued a final rule in the Federal Register adopting without change the requirements in the IFR.

Previously, this guidance document, issued in December 2004, served as the Small Entity Compliance Guide (SECG) for 21 CFR Part 1, Subpart J in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121). The SECG restated in plain language the legal requirements for the establishment and maintenance of records set forth in 21 CFR Part 1, Subpart J implementing section 414 of the FD&C Act, as added by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (Public Law 107-188). Because FDA issued an IFR and subsequent final rule amending certain requirements in 21 CFR Part 1, Subpart J to be consistent with the amendments to section 414(a) of the FD&C Act made by section 101 of FSMA, FDA is updating this SECG in April 2014 to provide guidance intended to help any entity, regardless of size, comply with this regulation. This document continues to serve as FDA's SECG for 21 CFR Part 1, Subpart J, including the amendments to this regulation made by the IFR and finalized without change.

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

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.

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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

Section 414(b) of the FD&C Act directs FDA to issue regulations that establish requirements regarding the establishment and maintenance of records – for not longer than two years – by persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food. To implement this provision, the Agency issued a final regulation on the establishment and maintenance of records in 2004 (69 FR 71561, Dec. 9, 2004) and certain parts of the regulations were subsequently corrected in 2005 (70 FR 8726, Feb. 23, 2005). The records that must be kept by these regulations are those that are needed by FDA for inspection, to allow FDA to identify the immediate previous sources and immediate subsequent recipients of food, including its packaging. This, in turn, will help address credible threats of serious adverse health consequences or death to humans or animals.

Through an interim final rule, FDA amended the records availability requirement in the regulations on establishment, and maintenance of records to implement the expansion of records access in the FD&C Act as amended by FSMA. 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. The FSMA amendments and interim final rule expand FDA's former records access beyond records relating to the specific suspect article of food to records relating to any other article of food that FDA reasonably believes is likely to be affected in a similar manner. In addition, FDA can access records relating to articles of food for which the Secretary believes that there is a reasonable probability that the use of or exposure to the article of food, and any other article of 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. This expanded records access further improves FDA's ability to respond to and contain threats of serious adverse health consequences or death to humans or animals.

III. Discussion This guidance was created to inform domestic persons in the U.S. who manufacture, process, pack, transport, distribute, receive, hold, or import food for humans or animals, and foreign persons who transport food in the U.S., about final regulations that establish requirements regarding the establishment and maintenance of records.

A. Establishment and Maintenance of Records

i. Who must establish and maintain records?

Domestic persons in the U.S. that manufacture, process, pack, transport, distribute, receive, hold or import food; foreign persons that transport food; and persons who place food directly in its finished container. For these regulations, the term persons include individuals, partnerships, corporations, and associations.

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ii. How is food defined for purposes of this regulation?

“Food” is defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321(f)], which defines “food” as: “(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.” Examples of “food” include:

- Dietary supplements and dietary ingredients
- Infant formula
- Beverages (including alcoholic beverages and bottled water)
- Fruits and vegetables
- Fish and seafood
- Dairy products and shell eggs
- Raw agricultural commodities for use as food or components of food
- Canned and frozen foods
- Bakery goods, snack food, and candy (including chewing gum)
- Live food animals
- Animal feeds and pet food

iii. Who is excluded entirely or in part from these regulations?

Excluded Entirely

- Farms
- Foreign persons, *except* for foreign persons who transport food in the U.S.
- Restaurants are excluded entirely. A combination restaurant/retail facility is excluded entirely if sales of food it prepares and sells to consumers for immediate consumption are more than 90 percent of its total food sales.
- Persons performing covered activities with food *to the extent* that the food is within the exclusive jurisdiction of the U.S. Department of Agriculture
- Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food for personal consumption
- Persons who receive or hold food on behalf of specific individual consumers and who are not also parties to the transaction and who are not in the business of distributing food (e.g., concierge in an apartment building)
- Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food packaging (the outer packaging of food that bears the label and does not contact the food), except for those persons who also engage in a covered activity with respect to food (see next page)

Excluded from the Requirement to Establish and Maintain Records, *but not the Record Availability Requirements for Existing Records*

- Fishing vessels not engaged in processing

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- Retail food establishments that employ 10 or fewer full-time equivalent employees
- Non-profit food establishments
- Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food are subject to the record availability requirements with respect to its packaging (the outer packaging of food that bears the label and does not contact the food)
- Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food contact substances other than the finished container that directly contacts the food
- Persons who manufacture, process, pack, transport, distribute, receive, hold, or import the finished container that directly contacts the food, except for those persons who place food directly in contact with its finished container
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Additional Partial Exclusions

- Persons who distribute food directly to consumers (the term *consumers* does not include businesses) are excluded from the requirement to establish and maintain records to identify the immediate subsequent recipients (they *are* subject to the requirements to identify the immediate previous sources)
- Persons who operate retail food establishments that distribute food to persons who are not consumers must establish and maintain records to identify the immediate subsequent recipients only to the extent the information is reasonably available

iv. What records must be established and maintained by non-transporters of food?

For non-transporters (i.e., persons who own food or who hold, manufacture, process, pack, import, receive, or distribute food for purposes other than transportation), the records have to:

1. Identify the immediate non-transporter previous sources, whether foreign or domestic, of all foods received, including:
 - The name of the firm; address; telephone number; fax number and e-mail address, if available;
 - Type of food, including brand name and specific variety (e.g., Brand X cheddar cheese, not just cheese; romaine lettuce, not just lettuce);
 - Date received;
 - Quantity and type of packaging (e.g., 12 oz. bottles);
 - Identify the immediate transporter previous sources, including the name, address, telephone number – and, if available, fax number and e-mail address. Persons who manufacture, process, or pack food also must include lot or code number or other identifier, if the information exists.

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2. Identify the immediate non-transporter subsequent recipients of all foods released, including:

- The name of the firm; address; telephone number; fax number and e-mail address, if available;
- Type of food, including brand name and specific variety;
- Date released;
- Quantity and type of packaging;
- Identify the immediate transporter subsequent recipients, including the name, address, telephone number – and, if available, fax number and e-mail address. Persons who manufacture, process, or pack food also must include lot or code number or other identifier, if the information exists.
- Information that is reasonably available to identify the specific source of each ingredient that was used to make every lot of finished product.

v. What records must be established and maintained by transporters of food?

The term “transporters” includes persons who have possession, custody, or control of an article of food in the U.S. for the sole purpose of transporting the food, whether by road, rail, water, or air. The term “transporters” also includes foreign persons that transport food in the U.S., regardless of whether the foreign persons have possession, custody, or control of food for the sole purpose of transporting it.

For transporters, records have to include names of the transporter’s immediate previous source and transporter’s immediate subsequent recipient, origin and destination points, date shipment received and date released, number of packages, description of freight, route of movement during the time the food was transported, and transfer point(s) through which the shipment moved.

vi. Do transporters have alternative methods of meeting the requirements of the rule?

Persons who have possession, custody, or control of food in the U.S. – for the sole purpose of transporting the food – or foreign persons who transport food in the U.S., regardless of whether they have possession, custody, or control of the food – for the sole purpose of transporting that food – have five alternative methods (depending on the mode of transportation) of meeting the requirements of the final rule.

Alternative Methods for Food Transporters

1. Establishing and maintaining the records described above
2. Establishing and maintaining specified information that is in the records required of roadway interstate transporters by the Department of Transportation’s Federal Motor Carrier Safety Administration contained in 49 CFR 373.101 and 373.103 as of December 9, 2004
3. Establishing and maintaining specified information that is in the records required of rail and water interstate transporters by the Department of Transportation’s

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Surface Transportation Board contained in 49 CFR 1035.1 and 1035.2 as of December 9, 2004

4. Establishing and maintaining specified information that is in the records required of international air transporters by the Warsaw Convention
5. Entering into an agreement with a non-transporter immediate previous source or immediate subsequent recipient (if located in the U.S.) to establish, maintain, or establish and maintain the required records in options 1, 2, 3, or 4. Section 1.352 of the final rule specifies what must be included in such agreements

B. How must the records be maintained?

FDA is specifying the information a covered entity must keep, but not specifying the form in which the records must be maintained. The records may be kept in any format, paper or electronic, provided they contain all the required information.

i. Can existing records be used to satisfy the requirements of these regulations?

The regulations do not require duplication of existing records, if these records contain all of the required information.

ii. How long must the records be retained?

The rule requires records to be created when food is received, released, or transported except to the extent the information is contained in existing records. The period for which the records must be retained depends on the perishability of the food:

Type of food	Record retention period for non-transporters	Record retention period for transporters or persons keeping records on their behalf
Food having significant risk of spoilage, loss of value, or loss of palatability within 60 days	6 months	6 months
Food having significant risk of spoilage, loss of value, or loss of palatability occurring after a minimum of 60 days, but within 6 months	1 year	1 year
Food having significant risk of spoilage, loss of value, or loss of palatability occurring no sooner than 6 months	2 years	1 year
Animal food, including pet food	1 year	1 year

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iii. Where must the records be retained?

At the establishment where the activities covered in the records occurred (onsite) or at a reasonably accessible location.

C. What are the record availability requirements?

When FDA has a reasonable belief that an article of food, and any other article of food that FDA reasonably believes is likely to be affected in a similar manner, is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, or when 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, any records or other information accessible to FDA under section 414 or 704(a) of the FD&C Act (21 U.S.C. 350c and 374(a)) must be made readily available for inspection and photocopying or other means of reproduction. Such records and other information must be made available as soon as possible, not to exceed 24 hours from the time of receipt of the official request, from an officer or employee duly designated by the Secretary of Health and Human Services who presents appropriate credentials and a written notice. The records requested may be related to the manufacture, processing, packing, transporting, distribution, receipt, holding, or importation of such an article of food that are maintained by, or on behalf of, an entity subject to the recordkeeping regulation, and at any location.

i. What records are excluded from records access?

Recipes, financial data, pricing data, personnel data, research data, and sales data are excluded from these requirements. A recipe is defined as the formula, including ingredients, quantities, and instructions necessary to manufacture a food product. Therefore, records relating only to the ingredients of a food product, and not the other two components of a recipe, are not excluded.

ii. What procedures does FDA intend to follow before requesting access to records?

FDA has issued a new guidance that presents additional information about records access. This document is available through links on FDA's homepage, www.fda.gov. Further, FDA's operational guidance to its staff regarding records access, which details the internal procedures the Agency follows, is provided in the Investigations Operations Manual (IOM) (Section 5.4.1.3) and the Regulatory Procedures Manual (RPM) (chapter 10-4), both available through links on FDA's homepage.

iii. How does FDA intend to make a request to access or copy records?

Once FDA makes the necessary determination following the procedures described in the IOM and RPM for making requests for records access under section 414(a) of the FD&C Act, an investigator or other FDA personnel – upon presentation of credentials – will

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provide a written notice (FDA 482c– Notice of Inspection – Request for Records) to the owner, operator, or agent in charge. The FDA investigator or FDA personnel will inform that person of the records request and FDA’s legal authority to obtain these records. FDA may request additional records related to the implicated article of food and other articles of food that FDA reasonably believes are likely to be affected in a similar manner at a later time under the same authority.

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

Information obtained under the records access provisions of sections 414(a) and 704(a) 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), Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)), and 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. 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.

D. What will happen if the required records are not established and maintained?

The failure to establish and maintain the required records or failure to make them available to FDA are prohibited acts under section 301(e) of the FD&C Act [21 U.S.C. 331(e)]. The Federal government can bring a civil action in Federal court to enjoin persons who commit a prohibited act. The Federal government also can bring a criminal action in Federal court to prosecute persons who commit a prohibited act.

E. When is compliance with the recordkeeping regulation required?

All businesses covered by this rule were required to comply by December 9, 2005, except small and very small businesses. Small businesses (11-499 full-time equivalent employees (FTEs)) were required to comply by June 9, 2006, and very small businesses (10 or fewer FTEs) were required to comply by December 11, 2006. The term, full-time equivalent employees or FTEs, means all individuals employed by the person claiming the exemption. The number of full-time equivalent employees is determined by dividing the total number of hours of salary or wages paid directly to employees of the person and of all of its affiliates by the number of hours of work in 1 year, 2,080 hours (i.e., 40 hours x 52 weeks). The interim final rule amending the records availability requirements to be consistent with changes to the FD&C Act made by FSMA became effective on March 1, 2012.