(11) Trailer initials/number;
(12) Container initials/number;
(13) No. packages; and
(14) Description of articles; or

(d) Establishing and maintaining records containing the following information currently required by the Warsaw Convention of international air transporters on air waybills:
(1) Shipper's name and address;
(2) Consignee's name and address;
(3) Customs reference/status;
(4) Airport of departure and destination;
(5) First carrier; and
(6) Description of goods; or

(e) Entering into an agreement with the nontransporter immediate previous source located in the United States and/or the nontransporter immediate subsequent recipient located in the United States to establish, maintain, or establish and maintain, the information in §1.352(a), (b), (c), or (d). The agreement must contain the following elements:
(1) Effective date;
(2) Printed names and signatures of authorized officials;
(3) Description of the records to be established and/or maintained;
(4) Provision for the records to be maintained in compliance with §1.360, if the agreement provides for maintenance of records;
(5) Provision for the records to be available to FDA as required by §1.361, if the agreement provides for maintenance of records;
(6) Acknowledgement that the nontransporter assumes legal responsibility under §1.363 for establishing and/or maintaining the records as required by this subpart; and
(7) Provision that if the agreement is terminated in writing by either party, responsibility for compliance with the applicable establishment, maintenance, and access provisions of this subpart reverts to the transporter as of the date of termination.

GENERAL REQUIREMENTS

### § 1.360 What are the record retention requirements?

(a) You must create the required records when you receive and release food, except to the extent that the information is contained in existing records.

(b) If you are a nontransporter, you must retain for 6 months after the dates you receive and release the food all required records for any food having a significant risk of spoilage, loss of value, or loss of palatability within 60 days after the date you receive or release the food.

(c) If you are a nontransporter, you must retain for 1 year after the dates you receive and release the food all required records for any food for which a significant risk of spoilage, loss of value, or loss of palatability occurs only after a minimum of 60 days, but within 6 months, after the date you receive or release the food.

(d) If you are a nontransporter, you must retain for 2 years after the dates you receive and release the food all required records for any food for which a significant risk of spoilage, loss of value, or loss of palatability does not occur sooner than 6 months after the date you receive or release the food, including foods preserved by freezing, dehydrating, or being placed in a hermetically sealed container.

(e) If you are a nontransporter, you must retain for 1 year after the dates you receive and release the food all required records for animal food, including pet food.

(f) If you are a transporter or nontransporter retaining records on behalf of a transporter, you must retain for 6 months after the dates you receive and release the food all required records for any food having a significant risk of spoilage, loss of value, or loss of palatability within 60 days after the date the transporter receives or releases the food. If you are a transporter, or nontransporter retaining records on behalf of a transporter, you must retain for 1 year after the dates you receive and release the food, all required records for any food for which a significant risk of spoilage, loss of value, or loss of palatability occurs only after a minimum of 60 days after the date the transporter receives or releases the food.

(g) You must retain all records at the establishment where the covered activities described in the records occurred (onsite) or at a reasonably accessible location.

(h) The maintenance of electronic records is acceptable. Electronic records are considered to be onsite if they are accessible from an onsite location.

### § 1.361 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 and other information accessible to FDA under section 414 or 704(a) of the Federal Food, Drug, and Cosmetic 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.

[77 FR 10662, Feb. 23, 2012]

### § 1.362 What records are excluded from this subpart?

The establishment and maintenance of records as required by this subpart does not extend to recipes for food as defined in § 1.328; financial data, pricing data, personnel data, research data, or sales data (other than shipment data regarding sales).

### § 1.363 What are the consequences of failing to establish or maintain records or make them available to FDA as required by this subpart?

(a) The failure to establish or maintain records as required by section 414(b) of the Federal Food, Drug, and Cosmetic Act and this regulation or the refusal to permit access to or verification or copying of any such required record is a prohibited act under section 301 of the Federal Food, Drug, and Cosmetic Act.

(b) The failure of a nontransporter immediate previous source or a nontransporter immediate subsequent recipient who enters an agreement under § 1.352(e) to establish, maintain, or establish and maintain, records required under § 1.352(a), (b), (c), or (d), or the refusal to permit access to or verification or copying of any such required record, is a prohibited act under section 301 of the Federal Food, Drug, and Cosmetic Act.

(c) The failure of any person to make records or other information available to FDA as required by section 414 or 704(a) of the Federal Food, Drug, and Cosmetic Act and this regulation is a prohibited act under section 301 of the Federal Food, Drug, and Cosmetic Act.

[80 FR 56144, Sept. 17, 2015

## Compliance Dates

### § 1.368 What are the compliance dates for this subpart?

The compliance date for the requirements in this subpart is December 9, 2005. However, the compliance dates for small and very small businesses are contained in paragraphs (a) and (b) of this section. The size of the business is determined using the total number of full-time equivalent employees in the entire business, not each individual location or establishment. A full-time employee counts as one full-time equivalent employee. Two part-time employees, each working half time, count as one full-time equivalent employee.

(a) The compliance date for the requirements in this subpart is June 9, 2006, for small businesses employing fewer that 500, but more than 10 full-time equivalent employees.

(b) The compliance date for the requirements in this subpart is December 11, 2006, for very small businesses that employ 10 or fewer full-time equivalent employees.

[69 FR 71651, Dec. 9, 2004, as amended at 70 FR 8727, Feb. 23, 2005]