



February 14, 2006

IMPORTANT INFORMATION

The United States Food and Drug Administration (FDA) has many new rules regarding the sale, storage and transportation of food products. Most of the products we sell and distribute (even though they are for pets) fall under the new guidelines.

If you process, transport, store or warehouse products you must register with the FDA. If you have not done so, please contact our office and we will help you. Retailers are generally excluded from this registration.

All of these new guidelines, registration requirements and record keeping rules are part of the FDA's New Food Bioterrorism Regulation. The purpose of the following information is to give you some idea of the record keeping guidelines.*

Who Must Establish and Maintain Records?

Domestic persons that manufacture, process, pack, transport, distribute, receive, hold or import food; foreign persons that transport food in the U.S. and all persons who place food directly in contact with its finished container. (The term "persons" includes individuals, partnerships, corporations, LLC's and associations) are subject to these record keeping regulations.

Excluded From The Requirement:

There are exclusions from the requirement to establish and maintain records but not the record availability requirement (in other words, there must be some record available). Retail establishments that employ 10 or fewer full-time equivalent employee are excluded at least for a short period of time.

Additional Partial Exclusions:

Persons who distribute food directly to consumers (the term consumer does not include businesses such as a distributor delivering to a retailer) are excluded from the requirement to establish and maintain records to identify the immediate subsequent recipients. **There are exceptions to this exclusion.** Basically, if a retailer has fewer than 10 full-time equivalent employees and sells products to the consumers in their original package, that retailer is excluded from the record keeping regulation.

What Records Must Be Established and Maintained?

1. You must know who brought the products to you. Requirements state that you must maintain records showing what you received- the exact name of the product, name of the transporter and manufacturer, date received, quantity, type of package, size, address, phone, fax, email and lot number.
2. When the distributor sells the product, the same information must be recorded to show to whom the product was delivered.
3. If a carrier other than the actual manufacturer delivers the product then complete information must be kept on that delivering carrier.

Simply stated, invoices received and sent must contain complete descriptive information and lot numbers. FDA wants to be able to track every single container through all steps from the manufacturer to the retailer.

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How Must The Records Be Maintained?

Guidelines are not clear. It is thought that any format that is readily available and retrievable will suffice. It is unclear exactly how long these records must be retained and is dependent on how perishable is the product. Records must be created when the food is received, released or transported unless this same information is contained in already existing records. The records must be retained at the establishment where the activities occur.

What Are The Record Availability Requirements?

If the FDA requests the records, they must be delivered within 24 hours of receipt of a formal request. Generally, an inspector or investigator will submit a Form FDA 4892 to the owner of the business (or whoever is in charge) and inform that person that these records have been requested. If these records are not made available, the Bioterrorism Act makes failure to produce these records a prohibited act and the federal government can bring civil as well as criminal action in Federal Court.

Compliance Deadlines:

- All businesses except as shown below must be in compliance within 12 months from 12/09/04.
- Small businesses with 11-499 employees must comply by 07/09/06.
- Very small businesses with 10 or fewer employees must comply by 12/09/07.

NOTE: The term full time equivalent employees (FTE's) means all the individuals employed by the person claiming exemption. The number of FTE's is determined by dividing the total number of hours of salary or wages paid directly to employees of the person and all of its affiliates by the number of hours of work in 1 year (2080 hours).

Additional Information:

Will retailers need to keep records?

The retailer must maintain records of receipt and release of the food. Simply stated, the person from whom the retailer buys must indicate the lot numbers or other tracking number on the invoice and the retailer must be able to show where the product is. As long as the retailer is selling to the end consumer, there is no requirement to keep records. Only when the retailer sells to another retailer or business establishment does the record keeping requirement for sales come into play. If a retailer sells bulk (out of a bulk bin or bulk container), there is no need for the retailer to maintain sales records other than this normally kept for business purposes. However, if a retailer re-packages food products and sells the re-packaged goods, then that retailer will probably be required to keep records as to the packaged product in inventory but not for the retail sale of the product.

Consignment Sales: If a manufacturer or distributor places product in a retail store on consignment, then the manufacturer still owns the product and the retailer as well as the manufacturer will be required to maintain records.

Returns By Consumers To Retailers:

If a food product is returned by a consumer to the retailer, the retailer may re-stock the item on the shelf providing that a record is maintained showing from whom the product was received, is clearly marked "consumer return", the date of the return, the disposition of the returned product and the lot number.

Returns By Retailers To Distributors or Manufacturers:

The same record keeping rules will apply. The distributor or manufacturer must maintain records showing from who the product was returned, date, lot number and specific product and who transported the product from retailer back to distributor. If the product is destroyed by the retailer or distributor, there

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must be a record maintained explaining the disposition including product name.. size, number units, lot number and how the product was destroyed.

Samples:

Samples carried by sales people, used at trade shows or handled in any manner are subject to this record keeping. Thus, the manufacturer and distributor must be able to track the food product to the person using the sample and if this sample is then given to someone else by the sales person, a record must be kept of that event.

General Information:

While complicated, these new regulations are simply meant to allow F.D.A. to identify where food products are at any given time. For the most part, retailers who sell or give away food products to the consumer are exempt for most record keeping. The questionable areas are where and when retailers repackaged products or sell or give product to someone other than a consumer

Manufacturers and distributors must keep records showing the receipt of food products (the transporter, date, size, name, lot number etc). This should be a part of the invoice received from the supplier. In addition, when the manufacturer or distributor ships or sells products to another “person” then records must be maintained on the movement of those products. Remember that a “person” is defined as a business (corporation, partnership, proprietorship, LLC, etc). The consumer who buys at retail is not included in the definition of “person.” A retailer or distributor who sells to a breeder may be required to keep these records if that breeder is buying as a “person” rather than as a consumer. For example, if a breeder is buying for use as well as resale or buys with a sales tax exemption number, then records must be kept at all levels because that breeder is then defined as a “person.”

Best Procedure:

The best way to approach this for distributors and manufacturers is simply to start keeping the records required and maintain those records. When food products are purchased by manufacturers, processors, packers or distributors, there needs to be clear documentation as to exactly what was purchased and how it was transported to the place of business. When the “person” sells the product, that same information should appear on the invoice to the retailer. Since the retailer is mostly exempt from record keeping, it should be acceptable to have the retailer keep track of those invoices and be able to reconcile products received with inventory on hand.

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