

FDA 306 Checklist For Food Manufacturers

Introduction	<p>The following checklist is based upon the FDA 306 final document, the FDA Final Rules slide presentation, “<u>Questions and Answers Regarding the Final Rule on Establishment and Maintenance of Records (Edition 2)- Nov 10, 2005</u>”, and detailed interviews with FDA personnel. Hyperlinks(<u>underlined and in blue</u>) will route the user to the exact documentation from the FDA’s documentation No.</p> <p>FDA 306 is a supplemental regulation. It does not replace other regulations.</p> <p>Sources : FDA 306 and FDA Q&A http://www.cfsan.fda.gov/~dms/frrecord.html http://www.cfsan.fda.gov/~dms/recguid2.html#sec-f</p> <p>Full 21 CFR (code of Federal Regulations) http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=1</p> <p>Prohibited Acts (Penalties for noncompliance) http://www.fda.gov/opacom/laws/fdcact/fdcact3.htm</p> <p>This is an evolving document so if you spot an error, hear contradictory information, or would just like discuss this with us further – Please email or call Dave Miller at davemiller@operationstech.com , 864-787-3971 .</p> <p>This information has been gathered primarily from FDA websites and supplemented by discussions with FDA agents. Operations Technologies assumes no legal responsibilities for actions or inactions taken by the reader as a result of this checklist.</p>		
Links to Definitions			
	Food		
	Farm		
	Non Transporter		
	Transporter		
	Manufacturing / processing		
	FTE – Full Time Equivalent Employee		
	“Reasonably Available Information”		
Applicability	-Check List For Manufacturers ONLY	Yes	No
	<p>Are you a manufacturer for purpose of FDA 306?</p> <p>(If not a manufacturer: this check list does not apply. It does NOT attempt cover distributors or transporters)</p> <p>Manufacturing/processing means making food from one or more ingredients, or synthesizing, [packing], preparing, treating, modifying, or manipulating food, including food crops or ingredients. Also includes vitamins and vitamin supplements.</p>	<input type="checkbox"/>	<input type="checkbox"/>

	<p>Examples of manufacturing/processing activities are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging.</p> <p>Note : Food samples intended for consumption (including consumption via test marketing, tasting at trade shows, and promotional marketing) are subject to this regulation</p>		
	<p>Manufacturer's exemptions and partial exemptions include :</p> <p>Persons who manufacture, process, pack, [] food in the United States are subject to the regulations in this subpart, unless you qualify for one of the exclusions.</p> <ul style="list-style-type: none"> - Nonprofits - Manufacturers EXCLUSIVELY covered by USDA - Retail manufacturers whose PRIMARY function is to sell to end consumers - Restaurants - Fishing Vessels <p>Please refer to in Sec. 1.327 for more complete information.</p>		
Prohibited Act	Civil and Criminal	Yes	No
	<p>Are your management and staff aware of the consequences of non-adherence ?</p> <p>Failing to collect and maintain the data required by FDA 306 is a "Prohibited Act"</p> <p>Persons committing a "Prohibited Act" are subject to one-year in jail and manufacturers are subject to a \$100,000 fine - per event or occurrence.</p> <p><i>Note : In previous FDA prosecution the cascading effects to stakeholders were often more damaging than the legal penalties. While 306 increases penalties it seems probable that stockholders, customers, and staff will continue to be more negatively impacted by implied risk and bad press than by the actual prosecution itself.</i></p> <hr/> <p>The exact wording is :</p> <p>As per SEC. 303. [21 U.S.C. 333]</p> <p>(a)(1) Any person who violates a provision of section 301 shall be imprisoned for not more than one year or fined not more than \$1,000, or both</p> <p>(3) Any manufacturer or distributor who violates section 301(t) because of a failure to make a report required by section 503(d)(3)(E) shall be subject to a civil penalty of not more than \$100,000.</p> <p>For more detail at the FDA source -> http://www.fda.gov/opacom/laws/fdcact/fdcact3.htm</p>	<input type="checkbox"/>	<input type="checkbox"/>

		Yes	No
Retention			
	Do you retain the records for 6 months for food that is likely to spoil within 60 days ?	<input type="checkbox"/>	<input type="checkbox"/>
	Do you retain the records for 1 year for food that is not likely to spoil within 60 days but likely to within 6 months ?	<input type="checkbox"/>	<input type="checkbox"/>
	Do you retain the records for 2 years for food that is not likely to spoil within 6 months?	<input type="checkbox"/>	<input type="checkbox"/>
Availability			
	Are all the documents dating back to the start of the required retention period (6 to 24 months) available?	<input type="checkbox"/>	<input type="checkbox"/>
	Are records on site or at a readily available locations and can they be retrieved and the specific data retrieved "as soon as possible" and no later than 24 hours after request? Note: There is no exemption for weekend or holiday requests. The SPECIFIC data must be retrieved, not lumped in a "show box" with all data	<input type="checkbox"/>	<input type="checkbox"/>
Security			
	Are backup copies of the FDA 306 documents stored in a secure location? (Not specifically required by FDA 306, however since the documentation is required, a secure copy seems advisable.)	<input type="checkbox"/>	<input type="checkbox"/>
Receiving			
	Do you record and maintain name of the firm, address, telephone number, and, if available, the fax number and e-mail address of the transporter immediate previous source (the transporter who transported the food to you) ? (1.337 (6))	<input type="checkbox"/>	<input type="checkbox"/>
	Do you have the physical address for the transporter (vs. a PO Box) ? (QA 34.9)	<input type="checkbox"/>	<input type="checkbox"/>
	Do you record and maintain name of the firm, address, telephone number and, if available, the fax number and e-mail address of the supplier ? (nontransporter) (1.337(1))	<input type="checkbox"/>	<input type="checkbox"/>
	Do you have the physical address for the nontransporter (vs. a PO Box) ? (QA 34.9)	<input type="checkbox"/>	<input type="checkbox"/>
	Do you record and maintain adequate description of the type of food received, to include brand name and specific variety (e.g., brand x cheddar cheese, not just cheese; or romaine lettuce, not just lettuce) ? (1.337 (2))	<input type="checkbox"/>	<input type="checkbox"/>
	Do you record and maintain the date you received each ingredient or food ?(1.337 (3))	<input type="checkbox"/>	<input type="checkbox"/>
	Do you record and maintain the lot or code number or other identifier of the food (to the extent this information exists) ? (1.337 (4))	<input type="checkbox"/>	<input type="checkbox"/>
	Do you record and maintain the quantity and how the food is packaged (e.g., 6 count bunches, 25 pound (lb) carton, 12 ounce (oz) bottle, 100 gallon (gal) tank); etc. (1.337 (5))	<input type="checkbox"/>	<input type="checkbox"/>
	Are materials received (transferred) from other subsidiaries (owned by the same parent) recorded at the same level as from an independent 3 rd party (QA 35.5)	<input type="checkbox"/>	<input type="checkbox"/>
	Is Packaging material that touches the food tracked as any other raw material (lot #, etc)	<input type="checkbox"/>	<input type="checkbox"/>
	Are food samples intended for consumption (including consumption via test marketing, tasting at trade shows, and promotional marketing) treated as any other	<input type="checkbox"/>	<input type="checkbox"/>

	raw material (lot tracking, etc) ? (QA 9.5)		
	Are the transporters of all samples recorded even if they arrive via mail, personal vehicle, taxi, etc ? (QA 9.1)		
	If the material arrives on a pallet or other container, do you take the pallet apart to collect the information? Other options include vendors who use SupplySync or otherwise provide the container's ingredients details. (QA 32.9)	<input type="checkbox"/>	<input type="checkbox"/>
	Note: Because the date, transporter, and vendor lot (etc) must be tracked through production/shipping (QA29.5), there are two likely acceptable scenarios. 1) The information must be physically attached to the container or 2) a new internal lot number is assigned and that information is attached to the material. The internal lot is then tracked via internal systems- For businesses of any volume, the later seems the most likely approach		
	Because date and transporter are key tracking components, the vendor's lot alone can not be used for tracing (Vendors lot A sent via carrier B on date C goes through a different transportation channel than Vendor lot A via carrier B on day C+1). This item was referred to and verified by an agent at FDA.		
Production		Yes	No
	Do you record and maintain information "reasonably available" to you to identify the specific source of each ingredient used to make every lot of finished product ? (1.345 (b)). Note : "reasonably available" has been defined as " does not require physical reconfiguration of the manufacturing facility " Information should include the shipper, transporter, receipt date of the actual inventory (not just the lot), the vendor's lot and manufacturing date. Note : Because the vendor's lot number , transporter, and receipt date were required to be collected at receiving – that information is , by definition, reasonably available.	<input type="checkbox"/>	<input type="checkbox"/>
	Are you recording ACTUAL quantities and lots as opposed to using backflushing? (We have not seen a SPECIFIC ruling that backflushing is no longer allowed but the existing requirements seem to imply it can no longer be used)	<input type="checkbox"/>	<input type="checkbox"/>
	Is packaging material that touches the food traced as an ingredient (QA 29.8 – part II , fyi, there were two 29.8 Q&A's) ?	<input type="checkbox"/>	<input type="checkbox"/>
	Do you trace "recycled" packing material that touches food and is returned for refilling (exemption may apply see QA 29.8) ?	<input type="checkbox"/>	<input type="checkbox"/>
	Are you storing the recipe, including the formula, ingredients, quantities, and instructions ?	<input type="checkbox"/>	<input type="checkbox"/>
	Are you recording the lots, etc of material used in manufacturing that are not ingredients? For instance the starch used in candy molding operations. The starch is not intentionally made part of the candy and the starch is reworked and replenished as needed. (QA 29.7)	<input type="checkbox"/>	<input type="checkbox"/>
Shipping			
	Do you record and store the name of the firm, address, telephone number, and, if available, the fax number and e-mail address of the customer ? (1.345 (1))	<input type="checkbox"/>	<input type="checkbox"/>
	Do you record and store an adequate description of the type of food released, to include brand name and specific variety (e.g., brand x cheddar cheese, not just cheese; or romaine lettuce, not just lettuce) ? (1.345 (2))	<input type="checkbox"/>	<input type="checkbox"/>
	Do you record and store the date you released the food ? (1.345 (3))	<input type="checkbox"/>	<input type="checkbox"/>
	Do you record and store the lot or code number or other identifier (1.345 (4)) of the shipped food ?	<input type="checkbox"/>	<input type="checkbox"/>

	Do you record and store the quantity and how the food is packaged (e.g., 6 count bunches, 25 lb carton, 12 oz bottle, 100 gal tank) ? (1.345 (5))	<input type="checkbox"/>	<input type="checkbox"/>
	Do you record and store name of the firm, address, telephone number, and, if available, the fax number and e-mail address of the transporter (1.345 (6))	<input type="checkbox"/>	<input type="checkbox"/>
Validation			
Scenario 1	<p>Tracing Back to Front</p> <p>At 7:00 PM on Saturday an FDA agent has informed you that there is a suspected problem with product "P" that was delivered to consumer "C" through one of 5 distributors approximately 23 months ago.</p> <p>The container size "S" was identified and the lot L was also identified.</p>		
Test Requirement 1	<p>No later than 7:00 PM Sunday , you are required to collect the following information :</p> <p>List and cross-reference all the transporters, their addresses and contact info, for all transporters who carried lot L.</p> <p>Identify all other customers who were shipped lot L or who were shipped anything in container from the same container lot as container S.</p> <p>Identify the size of lot L. Identify all items that included lot L. Identify all customers who were shipped lot L containing products.</p> <p>Identify the size of container S. Identify all items that included lot L. Identify all customers who were container S products.</p> <p>Identify the actual (backflush calculate) raw ingredients (I) and the quantity used to make lot L, and dates lot L was made.</p> <p>For ingredient I and container S, identify the delivery date, transporter, supplier , supplier's original lot number, manufacturing date, and quantity delivered</p>		
Scenario 2	<p>Tracing Front To Back</p> <p>At 7:AM on Sunday an FDA agent informs you that sometime in the last 2 years vendor V supplied you with material VM and lot VL in container size VS .</p>		
Test Requirement 2	<p>No later than 7AM Monday morning your must provide:</p> <p>All transporters and the dates they delivered vendor V material of lot VL in containers VS</p> <p>All production runs and recipes VL was used in. All end product, lots, and container sizes those production runs went into.</p> <p>All customers, transporters, who handled or received those products. The dates those products were shipped.</p>		