Date of This Update: December 2022

FDA Citations/Recalls/Warning Letters Relevant to Microbiological Issues

Reason for Recall/Warning Letter may be redacted to remove information identifying specific companies.
https://www.accessdata.fda.gov/scripts/ires/index.cfm

The purpose of this service is to provide helpful information related to recalls/citations/warning letters related to microbiological issues. It in not intended to replace the information provided by the FDA, nor is it guaranteed to be complete. Sponsors of the PMF are indicated at the bottom.

Product Type	Citation [C], Recall [R], Warning Letter [WL]	Reason for Citation/Recall/Warning Letter
Devices	**R**	Medical and surgical procedure trays and kits underwent certain manufacturing conditions that may result in the outer bag being incompletely sealed, which may result in a breach in the sterility of the kit.
Devices	**R**	During accelerated shelf-life extension studies it was noted that the final packaging was experiencing a potential of failure of the sterile packaging barrier which could result in a hazardous situation where the device is no longer sterile.
Devices	**R**	Boxes contain a reduced concentration of Nicotinamide Adenine Dinucleotide and does not provide enough of the blood factors necessary to support Haemophilus growth. The reduction could cause a false negative result for Haemophilus isolation in a clinical specimen.
Devices	**R**	Affected lots of the product are being recalled due to potential microbial growth in the fluid inside the device. if a compromised product is used by a child with a weakened immune system, an infection or other illness could occur.
Drugs	**R**	Lack of sterility assurance: Bags have the potential to leak.
Drugs	**R**	Lack of Assurance of Sterility: Leakage of 0.9% Sodium Chloride for Injection, 1L, 12pk Saline Solution.
Food	**R**	Potential to contain Salmonella
Food	**R**	Product may be contaminated with *Listeria monocytogenes*.
Food	**R**	Product found to be contaminated with *Listeria monocytogenes*
Veterinary	**R**	Potential Salmonella contamination of dry cat food
Food	**C**	You did not conduct operations under conditions and controls necessary to minimize the potential for growth or survival of microorganisms, allergen cross-contact and contamination of food.
Food	**WL**	Potential of product being contaminated with *L. monocytogenes*. Failure to comply with preventative controls. Environmental samples had the relevant contaminant. Some equipment was contaminated with *L. monocytogenes*. Sanitation efforts are inadequate. Food safety plan not prepared and implemented. Did not evaluate various raw materials for potential contaminants.
Drugs	**WL**	Product contaminated with *Providencia rettgeri*. Products grossly contaminated with bacterial and fungal species. Relied on COA from contract manufacturer rather than performing testing themselves, of particular concern was lack of testing for objectionable microorganisms. Microbiological release specification must be developed. Adequate assessment of contract manufacturers must be done.