

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 is not intended to replace the information provided by the FDA, nor is it guaranteed to be complete.

Product Type	Citation [C], Recall [R], Warning Letter [WL]	Reason for Citation/Recall/Warning Letter
Biologics	R	Leukoreduced Apheresis Platelets, PAS, collected in a manner that compromises the sterility of the collection system, were distributed.
Devices	R	Biological indicator (BI) used to promote growth of the G. stearothersophilus and B. atrophaeus spores was inconsistent in promoting growth throughout lot , some BIs within the lot performed as intended while others did not. When used to monitor steam and ethylene oxide sterilization cycles, the potential hazard is that the BI will show no growth indicating that the cycle was effective, even if it may not have been.
Devices	R	Packaging sterile barrier has been compromised. Open seals can lead to a loss of device sterility and may lead to infection
Devices	R	Blister package had an unsealed edge compromising sterility.
Devices	R	Specific lot have not been irradiated to eliminate pyronema and, therefore, the sterility of the affected products may be compromised.
Drugs	R	Lack of assurance of sterility: Bags have the potential to leak.
Drugs	W	concerns with: meeting appropriate microbial limits (compendial), freedom from objectionable microorganisms, cGMP training
Drugs	W	concerns with: sterility and sterilization processes, aseptic processes (inadequate media fills; did not simulate actual manufacturing process; poor aseptic behavior; inadequate facility area separations and size; inadequate environmental monitoring; inadequate manufacturing equipment; inadequate investigations and CAPA; inadequate cleaning and maintenance of equipment; ineffective quality systems)
Food/Cosmetics	R	Potential Salmonella contamination.
Food/Cosmetics	R	Possible pathogen grown and toxin formation in Salmon products
Food/Cosmetics	R	Products were found to be contaminated with Salmonella.

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