Date of This Update: January 18, 2023

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.

Product Type	Citation [C], Recall [R], Warning Letter [WL]	Reason for Citation/Recall/Warning Letter
Devices	**R**	Defect in sterile pouch seal, incomplete seal, of lighted Retractors, increases the risk of contamination, which can lead to post-operative infection.
Devices	**R**	All lots of [redacted] are being removed as a precautionary measure because tested endotoxin levels were higher than recommended by the current FDA regulatory guidance. In general, endotoxins have a potential to initiate inflammatory responses, ranging from a mild fever to potentially impact or damage to vital organs.
Drugs	**R**	Lack of Assurance of Sterility
Drugs	**W**	Concerns with: sterile compounding - products intended to be sterile were prepared, packed, or held under insanitary conditions, appropriate corrective action not taken after vermin were observed (source of microbial contamination), appropriate corrective action not taken after microbial contamination was found in ISO 5 aseptic processing area, operator placed gloved hands outside of ISO 5 area to retrieve supples without sanitizing hands prior to reentry into ISO 5 area.
Food/Cosmetics	**R**	Due to presence of mold (Aspergillus brasiliensis) and Ochratoxin A.