Date of This Update: February 2, 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
Biologics	**R**	Blood Products, which initially tested RPR reactive for syphilis, but had no confirmatory testing, were distributed.
Devices	**R**	Potential for sterile blades, within non-sterile SPT kits containing the blades, to puncture the outer foil layer causing a breach in the sterile packaging.
Devices	**R**	
Drugs	**R**	For one lot of CBC-3D Hematology Control, the Normal Level may exhibit hemolysis or deterioration due to microbial contamination.
Drugs	**R**	Lack of Assurance of Sterility: FDA inspection revealed insanitary conditions at the facility.
Drugs	**R**	Microbial Contamination of Non-Sterile Products: FDA Laboratory results found product to be contaminated with Bacillus lichenformis and Bacillus sonorensis.
Drugs	**W**	FDA laboratory analysis determined that a sample of your “redacted product was contaminated with bacillus sp., including B. cereus, B. amyloliquefaciens, B. atrophaeus, and others. A summary of results from testing retain samples of all drug product batches within expected period of marketing. You should test all appropriate quality attributes including, but not limited to, microbiological quality (total counts and identification of bioburden to detect any objectionable microbes) of each batch. If testing yields an OOS result, indicate the corrective actions you will take, including notifying customers and initiating recalls.
Drugs	**W**	During the inspection, the investigator noted serious deficiencies in your practices for producing drug products intended or expected to be sterile, which put patients at risk. 1. Firm used a (b)(4) for the purposes of product sterilization that was not appropriate for pharmaceutical use and the (b)(4) testing was inadequate. Therefore, you do not have assurance that the (b)(4) was integral throughout use. 2. Firm did not adequately disinfect materials or supplies during transfer from the ISO 8 cleanroom into higher classification areas. 3. Firm handled hazardous drug products without providing adequate containment, segregation, or cleaning of work surfaces and utensils to prevent cross-contamination. 4. Firm failed to perform adequate smoke studies under dynamic conditions to demonstrate unidirectional airflow within the ISO 5 area. Therefore, your products intended to be sterile are produced in an environment that may not provide adequate protection against the risk of contamination. 5. Media fills were not performed under the most challenging or stressful conditions. Therefore, there is a lack of assurance that your firm can aseptically produce drug products within your facility.
Drugs	**W**	Various claims made for antibacterial activity for colloidal silver. “Your Coated Silver product is not generally recognized as safe and effective for the above referenced uses and, therefore, this product is a “new drug” under section 201(p) of the Act, 21 U.S.C. 321(p).”
		Possible contamination with Listeria monocytogenes in frozen manicotti pasta.
Food/Cosmetics	**R**	Alfalfa sprouts have the potential to be contaminated with Salmonella.Alfalfa sprouts have the potential to be contaminated with Salmonella.
Food/Cosmetics	**R**	Infant formula potentially contaminated with Cronobacter sakazakii
Food/Cosmetics	**R**	Parsley imported from Mexico was found to be contaminated with Salmonella
Food/Cosmetics	**R**	Product(s) may be contaminated with Salmonella.

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**
		Sponsors of the Pharmaceutical Microbiology Forum