Date of This Update: February 27, 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**	[redacted] distributed [redacted]) involving a gel-clot potency test that did not meet product specifications during stability testing.
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**	A single CF-Q180AL colonovideoscope was utilized in a veterinary endoscopy procedure in advance of being assigned to a medical facility as a service loaner in error, potential for 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**	Firm needs: An action plan and timelines for conducting full chemical and microbiological testing of retain samples to determine the quality of all lots of drug product distributed to the United States that are within expiry as of the date of this letter.
Drugs	**R**	Lack of assurance of sterility: Medial fill with presence of Cupriavidus pauculus.
Drugs	**R**	Lack of sterility assurance
Food & Beverages	**W**	Your finished product testing records from January 1, 2021, to February 23, 2022, indicate that you detected Salmonella in your RTE peanut butter on numerous occasions, i.e., October 22 and December 15, 2021; and February 4, 9, 10, 20, and 21, 2022, and that your corrective actions were not sufficient to address the root cause of the contamination. You indicated that "[e]ven when the additional samples test negative, we destroy all (b)(4) production lots to provide further assurance we have bracketed and eliminated any potential contamination." However, your positive test results for lots for which Salmonella was previously not detected show the limitations of reliance on your testing program to identify contamination as a way to prevent contaminated products from reaching consumers. Further, the S. Senftenberg outbreak shows that neither your corrective actions nor your finished product testing was adequate to prevent contaminated product from reaching consumers and causing illnesses.
Food/Cosmetics	**R**	Parsley imported from Mexico was found to be contaminated with Salmonella
Food/Cosmetics	**R**	Product(s) may be contaminated with Salmonella.
Food/Cosmetics	**R**	Possible contamination with Shiga toxin-producing E. coli (non-O157:H7 STEC)
Food/Cosmetics	**R**	Raw material tested positive for Cronobacter sakazakii.
Human and Animal Food Operations	**W**	Laboratory Analysis of those samples identified Legionella pneumophilia serogroup 1 and Legionella spp. (hereinafter collectively called Legionella) in the potable water system of the vessels. FDA investigators also observed insanitary conditions related to the potable water systems onboard the vessels.
Veterinay	**R**	Top of the Rockies Alfalfa Cubes may have an issue of possible contamination that has caused Botulism in some horses.
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Product Type	**Citation [C], Recall [R], Warning Letter [WL]**	**Reason for Citation/Recall/Warning Letter**
Microbiologics		http://www.microbiologics.com
NOVATEK INTERNATIONAL		https://ntint.com/
STERIS		http://www.sterislifesciences.com/
vai VELTEK ASSOCIATES, INC.		http://www.sterile.com