Date of This Update: May 10, 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**	Some batches of product were not sterilized to their minimum sterilization specification.
Devices	**R**	Potential for packaging non-conformances directly related to the dual-barrier, sterile pouch packaging system. Non-conforming packaging may lead to a breach in the sterile barrier.
Devices	**R**	A packaging defect may compromise the sterile barrier.
Drugs	**R**	Lack of assurance of sterility.
Drugs	**R**	Lack of Assurance of Sterility: Potential presence of leaks originating from the Luer component.
Drugs	**WL**	Firm must provide: The chemical and microbiological quality control specifications you use to test and release each incoming lot of components for use in manufacturing.
Drugs	**WL**	“You failed to validate your water system and you lacked written procedures for the validation of the water system. Your firm lacked evidence to demonstrate that you could effectively control, maintain, sanitize, and monitor the system, so it consistently produces pharmaceutical grade water that, at a minimum, meets the Purified Water USP monograph and appropriately stringent microbiological limits. You must design and control your water system to reproducibly yield suitable water for use in production operations.”
Drugs	**WL**	Firm must provide: The chemical and microbiological quality control specifications you use to test and release each incoming lot of components for use in manufacturing.
Drugs	**WL**	Firm must provide: " A list of microbiological specifications (i.e., total counts, objectionable microorganisms), including test methods, used to analyze each lot of your drug products before a lot disposition decision.”

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Drugs	**WL**	"The inspection also documented that **(b)(4)** Nasal Spray drug product batch **(b)(4)**, released to the market, was also contaminated with yeast. Test results provided to you by your customer indicated at least three different samples of this lot having results for yeast greater than 20 CFU/g, with one as high as 70 CFU/g. We acknowledge that your customer voluntarily recalled the affected batch." "2. Your firm failed to establish and follow appropriate written procedures, designed to prevent objectionable microorganisms in drug products not required to be sterile (21 CFR 211.113(a)). Your firm failed to establish written, approved procedures to prevent microbial contamination during the manufacturing operations of nasal spray OTC drug products at your facility. Specifically, your firm did not have an environmental monitoring program, did not perform any microbiological testing of facilities or equipment, and did not have established cleaning procedures or records. These conditions and practices increased the risk of contamination of the drug products your firm manufactured. Furthermore, your firm failed to conduct appropriate laboratory testing of each batch of drug product required to be free of objectionable microorganisms (21 CFR 211.165(b))." " Complete investigations into all batches with potential objectionable microbial contamination or an OOS microbiological result (whether or not later invalidated). The investigations should detail your findings regarding the root causes of the contamination. • Appropriate microbiological batch release specifications (i.e., total counts, identification of bioburden to detect objectionable microbes) for each of your drug products. • All chemical and microbial test methods used to analyze each of your drug products. • A summary of results from testing retain samples of all drug product batches within expiry. You should test all appropriate quality attributes including, but not limited to, identity and strength of active ingredients, and 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." • A CAPA plan, based on the retrospective assessment of your cleaning and disinfection program, that includes appropriate remediations to your cleaning and disinfection processes and practices, and timelines for completion. Provide a detailed summary of vulnerabilities in your process for lifecycle management of equipment cleaning and disinfection. Describe improvements to your cleaning and disinfection program, including enhancements to cleaning effectiveness, improved ongoing verification of proper cleaning and disinfection execution for all products and equipment, and all other needed remediations.
Food & Beverages	**WL**	"Your pretzel hazard analysis in your food safety plan, dated March 21, 2022, did not consider pathogens such as *Salmonella* in your RTE seasoning ingredients to determine whether they require a preventive control. Your process does not apply a lethal treatment to any of your incoming raw materials and ingredients used in production of your RTE pretzels. Some of these seasoning ingredients (e.g., garlic parmesan, dill, and cinnamon) have been associated with pathogens such as *Salmonella*. Therefore, the pathogen of *Salmonella* is a known or reasonably foreseeable hazard. Further, a knowledgeable person manufacturing/processing food in your circumstances would identify pathogens as a hazard requiring a preventive control in these ingredients. Because these hazards are controlled at your suppliers, the appropriate type of control is a supply-chain control. A facility that identifies raw materials and other ingredients with hazards such as *Salmonella* that require a supply-chain-applied control must establish and implement a risk-based supply-chain program for those raw materials and ingredients (see 21 CFR 117.405(a)(1)). The supply-chain program must include using approved suppliers and conducting supplier verification activities (see 21 CFR 117.410)."

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Food & Beverages	**WL**	"Your **(b)(4)** validation for high pressure processing (HPP), titled "HPP Process Validation in Juice Products (Total Plate Count, E. coli and Listeria monocytogenes) Date: 11/14/2016", covers the following 5 juice products you manufacture: watermelon juice, Garden Green, Cleanse Health, mango juice, and cranberry Juice. This validation did not assess the efficacy of the HPP process throughout the 50-day shelf life of the products to ensure a minimum 5-log reduction in the pertinent microorganism throughout its shelf life when stored under normal and moderate abuse conditions, as required by 21 CFR 120.24(a)."
Food/Cosmetics	**R**	Possible contamination with Listeria monocytogenes
Food/Cosmetics	**R**	Mold growth on the outside of the bottle
Food/Cosmetics	**R**	Potential contamination with Listeria monocytogenes.
Food/Cosmetics	**R**	Product contains high levels of mold.
Food/Cosmetics	**R**	Product testing was found positive for Salmonella.
Food/Cosmetics	**R**	Infant Formula has the potential to be contaminated with Cronobacter spp.
Food/Cosmetics	**R**	Dietary ingredient had a Total Aerobic Microbial Count (TAMC) above firm's specification.
Food/Cosmetics	**R**	The firm was notified by one of their customers that their product test positive for Listeria monocytogenes.
Food/Cosmetics	**R**	Tattoo ink may be contaminated with bacteria
Food/Cosmetics	**R**	Tattoo ink contaminated with bacteria (Clostridium spp., Bacillus cereus, Streptococcus sanguinis, and Streptococcus alactolyticus)
Food/Cosmetics	**R**	Possible risk of pathogen contamination due to inadequate pasteurization.
Food/Cosmetics	**R**	Listeria monocytogenes
Foods	**C**	You did not conduct operations under conditions and controls necessary to minimize the potential for growth or survival of microorganisms.
Foods	**C**	You did not ensure that your cleaning compounds and sanitizing agents are safe and adequate under the conditions of use.
Foods	**C**	You did not implement your sanitation preventive control procedures.
Foods	**C**	You did not conduct operations under conditions and controls necessary to minimize the potential for growth or survival of microorganisms.
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NOVATEK INTERNATIONAL		https://ntint.com/
STERIS®		http://www.sterislifesciences.com/
vai VELTEK ASSOCIATES, INC.		http://www.sterile.com
Special Process Services, LC		**Special Process Services, LC**