Date of This Update: August 16, 2025

Regulator Findings Relevant to Microbiological Issues

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 regulators, nor is it guaranteed to be complete. The contents of this report are for educational purposes only.

Text in the Reason for Citation/Recall/Warning Letter column is from the indicated regulator. The regulators used are: CDSCO [https://cdsco.gov.in/opencms/opencms/en/Notifications/Alerts/], EMA [https://www.ema.europa.eu/en/human-regulatory-overview/compliance-overview], and FDA [https://datadashboard.fda.gov/ora/index.htm], [https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters], [https://www.accessdata.fda.gov/scripts/ires/index.cfm], [https://datadashboard.fda.gov/ora/cd/inspections.htm], and [https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/inspection-observations].

There may be some redactions to remove information identifying specific companies.

An "X" in the Sidecar column indicates that there is a YouTube video associated with the item. "Sidecars" videos are designed to be thought provoking, as per the white paper "Critical Scientific Thinking, SOPs and "Sidecars" at https://microbiologyforum.org/Articles_White_Papers/Critical_Scientific_Thinking_and_SOPs.pdf. Sidecars will be added periodically and listed here, at the PMF web site Training Tab [https://microbiologyforum.org/Training.html], and via online PMF Forum postings [https://microbiologyforum.org/Forum.html].

Sponsors of the PMF are indicated at the bottom.

CDSCO	Product Name	CDSCO NSQ Alert [CA], State NSQ Alert [SA]	Report for the Month of:	NSQ Result	Sidecar
CDSCO				Nothing new as of the date of this report.	
EMA	**Product Type**	**Non-compliance with GMP [NC]**	**Report #**	**Reason for Regulatory Action**	**Sidecar**
EMA				Nothing new as of the date of this report.	
FDA	**Product Type**	**Citation [C], Recall [R], Warning Letter [W]**	**Recall Details [R] FEI Number [C] MARCS-CMS [W]**	**Reason for Regulatory Action**	**Sidecar**
FDA	Food/Cosmetics	R	3026735880	potential Listeria Monocytogenes Contamination	
FDA	Devices	R	1000221450	Due to two issues: 1. Product contamination (biological foreign matter) that could compromise sterility.	
FDA	Food/Cosmetics	R	2000045075	Pecans have the potential to be contaminated with Salmonella	
FDA	Food/Cosmetics	R	3004284473	Clostridium botulinum (uneviscerated fish)	
FDA	Food/Cosmetics	R	3004345695	Supplier recalled ingredient used in finished product for possible Listeria monocytogenes contamination	
FDA	Food/Cosmetics	R	1627435	Pecans have the potential to be contaminated with Salmonella,	
FDA	Devices	R	1924669	The products may contain surface and subsurface contamination of Listeria monocytogenes.	
FDA	Devices	R	3024820181	The potential for risk of microbiological contamination of products due to inability to ensure sterility assurance throughout aseptic manufacturing.	
FDA	Food/Cosmetics	R	3015428950	Product tested positive for L. monocytogenes .	
FDA	Food/Cosmetics	R	3011916646	Salmonella Contamination. Firm detected salmonella on one batch of our SunBiotics Oat Milk Chocolate Covered Almonds.	
FDA	Biologics	R	3004548776	In this situation, Fenwal International (a Fresenius Kabi Company) is initiating a voluntary recall for one lot of Fenwal Blood-Pack Units with pre-sterilization bioburden test results that were too numerous to count (TNTC).	
FDA	Devices	R	3015942785	The firm issued a field safety notice after becoming aware of three lots of products not having quarterly dose audits being completed on time in the first quarter of 2024. Routine lot by lot testing was completed properly however the quarterly dose audit (sampling/testing to monitor the gamma sterilization process and confirm the validated parameters remain effective to assure sterility and bioburden reduction per requirements) was not completed on time.	
FDA	Drugs	R	3014780658	Lack of Assurance of Sterility: A market complaint was received for leakage and empty ampoule.	
FDA	Devices	R	1417592	Affected convenience kits contain BD ChloraPrep Clear - 1 mL Applicators, which were recalled by BD due to potential to exhibit an open seal on its packaging. This may constitute a breach to sterility, which may in turn lead to the infection related harms for the patient.	
FDA	Foods	C	3010620315	You are not monitoring the sanitation conditions and practices with sufficient frequency to assure conformance with Current Good Manufacturing Practices including prevention of cross-contamination from insanitary objects, maintenance of hand washing, hand sanitizing, and toilet facilities, protection of food, food packaging material, and food contact surfaces from adulteration and proper labeling, storage and use of toxic chemicals.	
FDA	Drugs	W	709488	"In response to this letter, provide: […] The chemical and microbiological quality control specifications you use to test and release each incoming lot of components for use in manufacturing."	
FDA	Drugs	W	707198	"Your firm lacked meaningful investigations of failed sterility and bioburden test results. For example: Sterility Failure Your quality unit (QU) did not adequately investigate a failed sterility test result for your (b)(4) drug product, VISCO SHIELD Topical Drops, lot V0724N. Your external testing laboratory performs two sterility tests: one for the contents within the syringe and the other for the sterility of the syringe and cap primary packaging components. Your external testing laboratory reported a sterility failure for the syringe and cap portion of the testing. You concluded in NCR 24014 that, because the contaminant was found only on the syringe and cap and not the contents of the syringe, the likely root cause of the sterility failure was laboratory contamination due to excessive handling during the test. However, your contract testing laboratory's investigation concluded that there was no laboratory error. You failed to resolve the conflicting root cause conclusions and did not extend your investigation to other potential sources of contamination or ensure it was of appropriate scope. Although the batch remained under your control, your QU had dispositioned this batch "USE AS IS" on September 30, 2024, to be distributed to the U.S. market. In your response to the sterility failure, we acknowledge your intention to create a specific procedure to address external laboratory out-of-specification (OOS) investigations. However, your investigation failed to consider conditions that led to the sterility failure or determine potential root causes to ensure effective CAPAs were promptly initiated. Additionally, you do not adequately address the potential non-integrity failure mode of the packaged finished drug product (e.g., breach in packaging integrity following (b)(4)). Bioburden OOS Your firm did not adequately investigate your firm's pre-sterilization bioburden results that exceeded their specifications (b)(4)) for VISCO SHIELD Topical Drops, lot V0724G. One sample exceeded the specification for the aerobic plate count test with a result of 570 CFU/sample and another sample exceeded the specification for the yeast and mold count test with a result of 334 CFU/sample. In your response to the bioburden OOS, your investigation fails to consider the conditions that led to the OOS. You do not identify the microbes recovered or determine resistance of any spore-forming microbes that may have been present. You also do not address potential root causes during the production process that could contribute to excess bioburden. Assessment of the number of types of microbes in pre-sterilization bioburden helps to determine whether the validated (b)(4) process continues to be capable of rendering the finished product sterile. Whenever an investigation lacks conclusive evidence of laboratory error, a thorough investigation of potential manufacturing causes must be performed. For more information about handling failing, OOS, out-of-trend, or other unexpected results and documentation of your investigations, see FDA's guidance document Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production at https://www.fda.gov/media/158416/download. While this guidance generally applies to chemistry-based laboratory testing, many of the principles are relevant to microbiological testing." […] "In response to this letter, provide: A list of chemical and microbial specifications, including test methods, used to analyze each batch of your drug products before a batch disposition decision. o An action plan and timelines for conducting full chemical and microbiological testing of retain samples to determine the quality of all batches of drug product distributed to the United States that are within expiry as of the date of this letter."	
FDA	Medical Devices	W	712573	"ii. The PQ protocol failed to include documentation of valid statistical rationale for cytotoxicity, endotoxin, and/or particulate testing. For example, the quantity tested per work order (66672, 66921, 66922) for cytotoxicity and endotoxin was (b)(4) and (b)(4) respectively and the quantity tested per work order (66675, 66919, 66920) for cytotoxicity, endotoxin, and particulate was (b)(4) and (b)(4), respectively." "For **(b)(4)**, an assessment of worst-case part justification was conducted and monitoring was put in place to control product release by assessing endotoxicity and cytotoxicity on a **(b)(4)** basis. In addition, you plan to require an update to this supplier's internal procedures to improve notification of triggers to their customers by 7/1/25."	
FDA	Drugs	W	710232	"2. Your firm failed to have, for each batch of drug product, appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient, prior to release (21 CFR 211.165(a)). You failed to adequately test batches of your drug products before release and distribution. For example, you stated during the inspection that you did not perform chemical or microbiological tests on your finished drug products prior to release and distribution into the U.S. market."	
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