Date of This Update: July 29, 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 is 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/cd/inspections.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" are designed to be thought provoking, as per the white paper "Critical Scientific Thinking, [illegible]hinking, SOPs and "Sidecars" [illegible]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	Gutwell Suspension, Bacillus clausii 2 billion spores/5ml	SA	May 2025	Total viable count Less than 2 billion spores/5ml.	
CDSCO	Bacillus clausii Bakteriya shtamminning polirezist Suspension, Bacillus clausii Bakteriya shtamminning polirezistent 2mlrd. Tirik bakteriyalar/5ml	SA	May 2025	Total viable count Less than 2 billion spores/5ml.	
CDSCO	Compound Sodium Lactate Injection IP (Ringer-Lactate Solution for injection)	SA	May 2025	Test for Sterility	
CDSCO	Compound Sodium Lactate Injection IP (Ringer's Lactate Solution for Injection) LP(R	SA	May 2025	Test for Sterility	
CDSCO	Sodium Chloride Injection IP 0.9% w/v (NS)	SA	May 2025	Test for Sterility	
CDSCO	Compound Sodium Lactate Injection IP (Ringer Lactate Solution for Injection.IP) RL	SA	May 2025	Test for Sterility	
CDSCO	Frusemide Injection I.P. 2 ml (Rusex Injection)	SA	June 2025	pH* and Sterility	
CDSCO	Methotrexate Injection IP 15 mg/ml (Folitrax-15)	SA	June 2025	Sterility	
CDSCO	Dexamethasone Sodium Phosphate Injection I.P. (Dexasun-For IM & IV use only)	SA	June 2025	Sterility and Assay for Dexamethasone Phosphate	
CDSCO	Dextrose Injection I.P 5% w/v (D5)	SA	June 2025	Sterility	
CDSCO	Sodium Chloride Injection I.P (0.9%w/v)NS	SA	June 2025	Sterility	
CDSCO	Methotrexate Injection IP 15 mg/ml (Folitrax-15)	SA	June 2025	Sterility	
CDSCO	Atropine Sulphate Injection I.P (Cyropine)	SA	June 2025	Sterility	
CDSCO	Sodium Chloride Injection I.P. (NS)	SA	June 2025	Sterility	
CDSCO	Sodium Chloride Injection IP 0.9% w/v (NS)	SA	June 2025	Sterility	
CDSCO	Pheniramine Maleate Injection IP (Care Vit)	SA	June 2025	Sterility	
CDSCO	Cyanocobalamin I.P.- Cyanobe Injection I.P. (VITAMIN B12 INJ)	SA	June 2025	Sterility* and "Assay for Anhydrous Cyanocobalamin"	
CDSCO	Ofloxacin and Dexamethasone Ophthalmic Solution	SA	June 2025	Sterility	
CDSCO	Pantoprazole Sodium for Injection (Petabite-40)	SA	June 2025	Sterility	
CDSCO	Bupivacaine Hydrochloride in Dextrose Injection USP 4 ml	CA	May 2025	pH, Bacterial Endotoxins Test, Particulate Matter in Injections and Description	
CDSCO	Sodium Chloride Injection I.P. (0.9% w/v),NS	CA	May 2025	Sterility & Description	
CDSCO	Disposable Syringes (5ml) (SUI)	CA	May 2025	Sterility	
CDSCO	Oxytocin Injection I.P. (Oxytocin Vet. 100 ml Vial)	CA	May 2025	pH and Sterility	
CDSCO	Injection Oxytocin Vet. 50 ml Vial	CA	May 2025	pH and Sterility	
CDSCO	SPORLAC Tablets (Tablets of Probiotics)	CA	May 2025	"Identification of Bacillus clausii"	
CDSCO	Haematinic Capsules (R.B. TONE)	CA	May 2025	"Microbial limit test (Total combined yeasts/moulds count)"	
CDSCO	Gentamicin Injection IP (Gentacoo)	CA	June 2025		
CDSCO	Pantoprazole Sodium for Injection (K Pan-IV Injection)	CA	June 2025	Sterility	
CDSCO	Infusion Set-NV	CA	June 2025	Sterility	
CDSCO	0.45 % w/v Sodium Chloride and 5 % w/v Dextrose Injection I.P. (0.45 % DNS), 500 ml	CA	June 2025	Test for Sterility	

EMA	Product Type	Non-compliance with GMP [NC]	Report #	Reason for Regulatory Action	Sidecar
EMA	Human medicinal products	NC	MT/002NCR/2025	1.8.2 Microbiological non-sterility 1.8.3 Chemical/Physical Nature of non-compliance: Following an on-site inspection at Viridis Pharma (Pty) Ltd. in South Africa (10–13th April 2025) for the analytical testing (chemical and microbiological) of non-sterile dosage forms, specifically for Cannabis products (inflorescence), [illegible]	
EMA	Human medicinal products	NC	PE010-4837	Nature of non-compliance: During the inspection, 28 deficiencies were identified, 4 of them has been classified as critical and 3 as major. [illegible]	

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	3000906985	Potential to be contaminated with Listeria monocytogenes.	
FDA	Food/Cosmetics	R	3017860622	Product may be contaminated with spoilage organisms.	
FDA	Devices	R	2925203	Salmonella. The firm was notified by the FDA that the product may be contaminated with Salmonella.	
FDA	Devices	R	3150138	Affected products contain Staphylococcus epidermidis instead of the expected Brevundimonas diminuta. This may cause the user's quality control to fail and delayed diagnosis of the patient.	
FDA	Food/Cosmetics	R	1011807	Potential Listeria monocytogenes Contamination.	
FDA	Veterinary	R	3006117352	Lack of assurance of Sterility.	
FDA	Food/Cosmetics	R	3004735171	Potential to be contaminated with Listeria monocytogenes.	
FDA	Food/Cosmetics	R	3025411927	Product may be contaminated with Listeria monocytogenes.	
FDA	Food/Cosmetics	R	3009214952	Listeria monocytogenes. The firm was notified by their supplier that the product is contaminated with Listeria monocytogenes.	
FDA	Biologics	R	3004548776	In this situation, [redacted] is initiating a voluntary recall for one lot of [redacted]Blood-Pack Unit due to an elevated presence of bacteria that was found in pre-sterilization in-process testing during the manufacture of this BPU lot.	
FDA	Devices	R	2005816	Due to a manufacturing issue, the disinfecting cap for needle-free connectors may have an incomplete seal between the foil lid and plastic container, which may result in isopropyl alcohol evaporation from the sponge, which may result in inadequate disinfection.	
FDA	Food/Cosmetics	R	3010292778	Potential to be contaminated with Bacillus cereus and may be spoiled.	
FDA	Devices	R	1610287	Due to the potential that some units within specific lots were damaged during the manufacturing process. The area of damage is within the same area of the [illegible] While the damage in the folding is visibly noticeable, due to risk of sterility being compromised.	
FDA	Devices	R	2124215	Potential for hole in the Tyvek layer of the sterile barrier pouch, which may compromise device sterility. Issue could potentially lead to systemic infection and sepsis in worst case scenario. Potential punctures may go undetected in clinical settings [illegible]	
FDA	Food/Cosmetics	R	2919839	Potential contamination with Salmonella.	
FDA	Food/Cosmetics	R	3013418413	Cucumbers have the potential to be contaminated with Salmonella	
FDA	Food/Cosmetics	R	3012337333	Potential to be contaminated with Listeria monocytogenes	
FDA	Drugs	R	2280705	Microbial Contamination of Non-Sterile Products: Fungal contamination of nasal swabs. Microbial Contamination of Non-Sterile Products: Fungal contamination of infant oral swabs.	
FDA	Food/Cosmetics	R	3004329004	Potential Salmonella contamination.	
FDA	Food/Cosmetics	R	3012869379	Cucumbers have the potential to be contaminated with Salmonella.	
FDA	Food/Cosmetics	R	3004090157	Listeria monocytogenes. During routine testing the firm received positive test results of Listeria monocytogenes on their finished product.	
FDA	Drugs	R	3022461164	Lack of Assurance of Sterility: A recent FDA inspection revealed concerns with the sterile manufacturing process.	
FDA	Food/Cosmetics	R	3002960799	Salmonella. The firm received cucumbers which were recalled due to possible Salmonella. The cucumbers were used to make Sushi.	
FDA	Food/Cosmetics	R	2925189	Potential contamination with Salmonella.	
FDA	Food/Cosmetics	R	3003884650	Products have the potential to be contaminated with Listeria monocytogenes	X
FDA	Food/Cosmetics	R	3002861103	Product has Salmonella contamination	
FDA	Drugs	R	3006727872	Lack of Assurance of Sterility	
FDA	Food/Cosmetics	R	3001158718	Clostridium botulinum (unrefrigerated fish)	
FDA	Drugs	R	3013748690	Lack of assurance of sterility: pinholes, within the finger boxes used during the Form Fill Seal process resulting in leaks.	
FDA	Drugs	R	3012825261	Microbial contamination of non-sterile products: tablets may exhibit black spots due to microbial contamination.	
FDA	Drugs	R	3001451488	Lack of Assurance of Sterility	
FDA	Devices	R	3003413525	Devices contain potentially out-of-specification levels of endotoxins and lack of assurance of sterility.	
FDA	Devices	R	3003418525	Lack of sterility assurance.	
FDA	Food/Cosmetics	R	3004612286	Cucumber in salad may be contaminated with Salmonella	
FDA	Food/Cosmetics	R	3012106609	Potential Salmonella contamination	
FDA	Drugs	R	3003176899	Lack of Assurance of Sterility	
FDA	Food/Cosmetics	R	3011841393	Potential contamination with Salmonella	
FDA	Biologics	R	3001431955	Apheresis Red Blood Cells, Leukocytes Reduced, collected in a manner that compromises the sterility of the collection system, were distributed. [illegible]	
FDA	Biologics	R	1573019	Leukoreduced Apheresis Red Blood Cells, collected in a manner that compromises the sterility of the collection system, were distributed.	
FDA	Food/Cosmetics	R	3012221339	Potential to be contaminated with Salmonella	
FDA	Food/Cosmetics	R	1000126718	Potential contamination with Pseudomonas aeruginosa.	
FDA	Food/Cosmetics	R	1053492	Pseudomonas in Mineral Water. The firm was notified by their distributor that product placed on hold was released and shipped to customers.	
FDA	Food/Cosmetics	R	1000135865	Salmonella. Greek Salad Kit made with recalled cucumbers sourced from Bedner Grower's Company which may be contaminated with Salmonella and implicated in an ongoing outbreak.	
FDA	Food/Cosmetics	R	1000135693	Contains cucumber contaminated with Salmonella recalled by Bedner Growers Inc.	
FDA	Devices	R	3013407149	Due to non-sterile parts being included being labeled as sterile	
FDA	Devices	R	3016114779	Contact lens insertion solution may lack sterility.	
FDA	Devices	R	2014487482	Sterility assurance for Ophthalmic knives.	
FDA	Food/Cosmetics	R	1219867	Contaminated with Salmonella	
FDA	Food/Cosmetics	R	1000138473	Cucumbers have the potential to be contaminated with Salmonella	
FDA	Food/Cosmetics	R	3016691197	Potential Salmonella Contamination	
FDA	Food/Cosmetics	R	3010052930	Product has Salmonella contamination	
FDA	Food/Cosmetics	R	1018894	Product has potential contamination with Salmonella	
FDA	Devices	R	2429304	Recent post-market surveillance data suggests a possible association of higher microbial contamination levels from TJF duodenoscopes when manual cleaning was delayed beyond one hour and a precleak was performed, compared to those TJF duodenoscopes where manual cleaning began within one hour after patient procedure.	
FDA	Biologics	R	3016604	Salmonella. Greek Salad Kit made with recalled cucumbers from Bedner Grower's Company which was contaminated with Salmonella and implicated in an ongoing outbreak.	
FDA	Food/Cosmetics	R	1002298	Cucumbers may be contaminated with Salmonella	
FDA	Food/Cosmetics	R	3003328123	Listeria Monocytogenes detected on food contact surfaces in Ready To Eat sandwich manufacture facility.	
FDA	Food/Cosmetics	R	3012603930	Due to potential Salmonella Contamination	
FDA	Food/Cosmetics	R	1120008	Salmonella. The firm received cucumbers produced by Bedner Farms.	
FDA	Food/Cosmetics	R	2316750	Potential Salmonella contamination.	X
FDA	Foods	C	1000113630	You did not clean and sanitize your utensils or equipment as frequently as necessary to protect against contamination of food.	
FDA	Foods	C	3000106003	You did not maintain your plant in a clean and sanitary condition.	
FDA	Foods	C	3002534474	You did not conduct operations under conditions and controls necessary to minimize the potential for growth or survival of microorganisms.	
FDA	Devices	C	1000139887	A process whose results cannot be fully verified by subsequent inspection and test has not been adequately validated according to established procedures.	
FDA	Foods	C	3003455128	You did not conduct operations under conditions and controls necessary to minimize the potential for growth or survival of microorganisms and deterioration of food.	
FDA	Foods	C	3011873190	You did not ensure that raw materials, other ingredients, or rework were not contaminated with undesirable microorganisms and extraneous materials.	
FDA	Foods	C	3011873192	You did not conduct operations under conditions and controls necessary to minimize the potential for growth or survival of microorganisms and deterioration of food.	
FDA	Devices	C	3013975539	Procedures to control environmental conditions have not been adequately established.	
FDA	Foods	C	3011485229	You did not ensure that your cleaning compounds and sanitizing agents are safe and adequate under the conditions of use.	
FDA	Foods	C	3011485229	You did not conduct operations under conditions and controls necessary to minimize the potential for growth or survival of microorganisms and deterioration of food.	
FDA	Foods	C	3001178690	You did not conduct operations under conditions and controls necessary to minimize the potential for [illegible] contamination of food.	
FDA	Foods	C	3006084791	You did not ensure [illegible] and have records documenting food hygiene and food safety training.	
FDA	Foods	C	3013008421	You did not conduct operations under conditions and controls necessary to minimize the potential for growth or survival of microorganisms and deterioration of food.	X
FDA	Foods	C	3006637230	You did not conduct operations under conditions and controls necessary to minimize the potential for growth or survival of microorganisms and deterioration of food.	
FDA	Drugs	C	3002907007	Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include validation of the aseptic [illegible]	
FDA	Drugs	C	3002693195	Employees are not [illegible] Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards [illegible]	
FDA	Foods	C	3011086300	You did not maintain [illegible] necessary to protect against contamination of food.	
FDA	Drugs	W	706287	1. Your firm failed to establish adequate written procedures for production and process control designed to assure that the drug products you manufacture have the identity, strength, quality, and purity they purport or are represented to possess [illegible]	
FDA	Drugs	W	707024	3. Your firm failed to [illegible]	
FDA	Drugs	W	704371	1. Your firm failed to [illegible] [illegible] operators. We observed cleaning deficiencies and variability between operators, including wiping technique, using the same cleaning cloths for multiple areas, and failure to clean on top of the overhead light casings of the filling line. Further, the disinfection efficacy studies for (b)(4) did not adequately address all materials of the filling line, including but not limited to, (b)(4) (filling equipment), (b)(4) and (b)(4), and (b)(4) hose). In addition, your (b)(4) room decontamination validation is deficient (e.g., biological indicator locations are not adequately justified). Your response is inadequate. You commit to conduct a comprehensive review and assessment of cleaning and disinfection practices; however, you fail to investigate the impact on the products in the U.S. Market. In addition, a retrospective review for only extraneous chromatographic peaks is not sufficient to determine if deficient cleaning practices contribute to finished product that does not meet established specifications. In response to this letter, provide the following: 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 and disinfection effectiveness; improved ongoing verification of proper cleaning and disinfection execution for all products and equipment; and all other needed remediations. Additional Guidance on Aseptic Processing See FDA's guidance document Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice to help you meet the CGMP requirements when manufacturing sterile drugs using aseptic processing at https://www.fda.gov/media/71026/download. Quality Systems Your firm's quality systems are inadequate. For guidance on establishing and maintaining CGMP-compliant quality systems, see FDA's guidances: Q9 Quality Risk Management at https://www.fda.gov/media/167721/download and Q10 Pharmaceutical Quality System at https://www.fda.gov/media/71553/download.	
FDA	Drugs	W	701278	2. Your firm failed to establish laboratory controls that include scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity (21 CFR 211.160(b)). In addition, you were unable to provide documentation to demonstrate that your (b)(4) water system is adequately monitored and tested for conductivity or microbiology. (b)(4) water from this system was used as a component in the drug products you manufacture and distribute. In your response, you state that the justification for product sampling is being evaluated. You also state that the SOP governing the frequency, methods, and responsibility for performing water sampling would be reviewed. Your response is inadequate. You did not provide or commit to provide any justification for your drug product sampling plans. Additionally, you did not provide or describe a specific plan or timeline for monitoring to ensure the suitability of your (b)(4) water. Further you did not consider testing retains or a retrospective review of distributed batches where there was incomplete or inadequate water testing. Without appropriate sampling plans, you do not have scientific evidence to support whether your drug products meet their established finished product chemical and microbiological specifications. Product released without adequate determination of homogeneity or microbiological evaluation poses a risk to patients. In response to this letter, provide: • A comprehensive, independent assessment of your in-process monitoring and sampling operations, focusing on each upstream process step that can introduce variability. Provide your remediation plan to improve: (1) in-process detection of variation; (2) upstream controls; and (3) sampling plans. • 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. o A summary of all results obtained from testing retain samples from each batch. If such testing reveals substandard quality drug products, take rapid corrective actions, such as notifying customers and product recalls. • A procedure for your water system monitoring that specifies routine microbial testing of water to ensure its acceptability for use in each batch of drug products produced by your firm. • The current action/alert limits for total counts and objectionable organisms used for your (b)(4) Water system. Ensure that the total count limits for your (b)(4) water are appropriately stringent in view of the intended use of each of the products produced by your firm. • A procedure governing your program for ongoing control, maintenance, and monitoring that ensures the system consistently produces water that meets (b)(4) Water, (b)(4) monograph specifications and appropriate microbial limits.	
FDA	Animal and Veterinary	W	694680	Undesirable Microorganisms in Your Pet Food and Your Processing Environment You manufacture raw pet food and the practices described above are ways in which the pet food you manufacture could become contaminated by undesirable microorganisms. Undesirable microorganisms include microorganisms that are pathogens, that subject animal food to decomposition, that indicate that animal food is contaminated with filth, or that otherwise may cause animal food to be adulterated.5 As described above, FDA analysis of four lots of your pet food purchased at retail revealed that these lots contained undesirable microorganisms, specifically, Salmonella Newport, L. monocytogenes, Salmonella Kentucky, and Salmonella Typhimurium. In addition, described above are environmental samples that FDA collected during the inspection that revealed the presence of L. monocytogenes on seven surfaces in your facility, including Zone (b)(4) food-contact surfaces. FDA's WGS analysis determined two environmental subsamples are a genetic match to the L. monocytogenes isolate found in one of the pet foods FDA sampled. The presence of undesirable microorganisms in your finished product and processing environment, including food-contact surfaces, is further evidence of the significance of your violations of the animal food Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls requirements and demonstrates that your practices are not adequate to prevent or mitigate biological hazards. We encourage you to pursue corrective actions and will verify their adequacy during a future inspection.	
FDA	Drugs	W	706053	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. Your firm also failed to conduct, for each batch of drug product, appropriate laboratory testing, as necessary, required to be free of objectionable microorganisms (21 CFR 211.165(a) and 211.165(b)). Your firm failed to conduct adequate finished product release testing for each batch of your drug products, including but not limited to, testing the identity and strength of the active ingredients, and testing for objectionable microorganisms. Without adequate finished product release testing, you do not have scientific evidence that each batch of drug product conforms to appropriate specifications before release.	
FDA	Drugs	W	708259	1. Your firm failed to conduct for each batch of drug product, appropriate laboratory testing, as necessary, required to be free of objectionable microorganisms (21 CFR 211.165(b)). You manufacture over-the-counter (OTC) sunscreen and (b)(4) drug products. Your (b)(4) antiseptic is labeled for hospital use only and used to prepare skin prior to surgery. You released your (b)(4) drug product batches without testing for microbiological quality. For example, the batch record for finished product batch (b)(4), manufactured in September 2024 and distributed to a children's hospital, only lists finished drug product tests for (b)(4) assay, color, odor, appearance, and percentage of (b)(4). Without testing each batch prior to release, you did not have scientific evidence that all drug product batches were free of microbial contamination that is objectionable in view of its intended use. In your response, you state that your (b)(4) product contains (b)(4) and (b)(4), which are bactericidal. You indicate that you "think that the requirement to have finished product tested for presence of objectionable microorganisms is not necessary." You commit to testing your finished drug product for objectionable microorganisms prior to releasing any future batches. Your response is inadequate. You did not provide an appropriate scientific basis to support that your finished drug products are free from microbial growth or survival. Additionally, you did not provide any retrospective testing to support the quality of your drug products currently on the market. In response to this letter, provide the following: A list of chemical and microbiological specifications, including test methods, used to analyze each batch of your drug products before batch disposition decisions. 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 products distributed in the United States that are within expiry as of the date of this letter. o A summary of all results obtained from retain samples from each batch. If such testing reveals substandard quality drug products, take rapid corrective actions, such as notifying customers and product recalls. In response to this letter, provide the following: […] The chemical and microbiological quality control specifications you use to test and release each incoming lot of components for use in manufacturing.	
FDA	Food & Beverages	W	698230	During our inspection of your farm, FDA investigators observed serious violations of the Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation regulation (the Shell Egg regulation), Title 21, Code of Federal Regulations, Part 118 (21 CFR Part 118).	
FDA	Drugs	W	709859	2. Your firm failed to ensure that laboratory records included complete data derived from all tests necessary to ensure compliance with established specifications and standards (21 CFR 211.194(a)). You failed to accurately document microbiology testing results. In addition, test results are not verified by a second person for accuracy. Specifically, on November 6, 2024, your analyst recorded fewer colony forming units for active air environmental monitoring samples than what was observed by our investigator during the examination. An independent review of the plate count by a second analyst to assure accuracy of the data was not conducted. Reliability of data is fundamentally compromised when there is a failure to record or maintain complete and accurate records of test results. Furthermore, the lack of reliable data compromises the quality unit's ability to exercise its function of ensuring compliance to applicable standards. Your initial response acknowledged "a secondary, contemporaneous verification of environmental monitoring samples is fundamental to maintaining the integrity of such data." You also committed to revise your procedures to require a second person review for all tests and to perform a retrospective review of "microbiology laboratory activities to identify activities that are not currently recorded electronically or contemporaneously." Your initial response was inadequate because it failed to address the misread plate counts observed during the inspection for viable air and identify corrective and preventative actions for this failure. Moreover, your response lacks an assessment of potential data integrity concerns associated with one-person verification. In response to this letter, provide: A comprehensive assessment of your laboratory practices, procedures, methods, equipment, documentation, and analyst competencies. Based on this review, provide a detailed plan to remediate and evaluate the effectiveness of your laboratory system. […] In your responses, you state that section 6.8.7.5 of your SOP-000189 "Use, Preparation, and Storage of QC – Microbiology Laboratory Media" has been revised. However, the revision does not clearly define when or how the second verifier will "…visually verify the presence or absence of microbiological growth…." Nor does the SOP address required timeframes as to when the second person will verify growth and ensure data is entered timely and correctly in the (b)(4) system. As written, the SOP fails to ensure contemporaneous QC review of plate counts and data accuracy.	
FDA	Drugs	W	699291	C. Violations of the FDCA Adulterated Drug Products The FDA investigator noted that drug products intended or expected to be sterile were prepared, packed, or held under insanitary conditions, whereby they may have become contaminated with filth or rendered injurious to health, causing your drug products to be adulterated under section 501(a)(2)(A) of the FDCA. For example, the investigator noted: 1. Aseptic operators reaching into the ISO 5 laminar flow hood past their elbows during aseptic production. However, microbial contamination action limit for personnel monitoring of the elbows is (b)(4). This practice may introduce contamination into the ISO 5 work area. 2. Your 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. 3. Your 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. The FDA investigator also noted CGMP violations at your facility, that caused your drug product(s) to be adulterated within the meaning of section 501(a)(2)(B) of the FDCA. The violations include, for example: 1. Your firm failed to thoroughly investigate any unexplained discrepancy or failure of a batch or any of its components to meet any of its specifications, whether or not the batch has already been distributed (21 CFR 211.192). 2. Your firm failed to establish adequate written procedures for production and process control designed to assure that the drug products you manufacture have the identity, strength, quality, and purity they purport or are represented to possess (21 CFR 211.100(a)). 3. Your firm failed to ensure that each person engaged in the manufacture, processing, packing, or holding of a drug product has the education, training, and experience, or any combination thereof, to enable that person to perform his or her assigned functions (21 CFR 211.25(a)). 4. Your firm failed to establish an adequate system for monitoring environmental conditions in aseptic processing areas (21 CFR 211.42(c)(10)(iv)). 5. Your firm failed to clean, maintain, and, as appropriate for the nature of the drug, sanitize and/or sterilize equipment and utensils at appropriate intervals to prevent malfunctions or contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements (21 CFR 211.67(a)). 6. Your firm failed to establish and follow appropriate written procedures that are designed to prevent microbiological contamination of drug products purporting to be sterile, and that include validation of all aseptic and sterilization processes (21 CFR 211.113(b)). Outsourcing facilities must comply with CGMP requirements under section 501(a)(2)(B) of the FDCA. FDA's regulations regarding CGMP requirements for the preparation of drug products have been established in 21 CFR parts 210 and 211. FDA intends to promulgate more specific CGMP regulations for outsourcing facilities. FDA has issued a revised draft guidance, Current Good Manufacturing Practice — Guidance for Human Drug Compounding Outsourcing Facilities under Section 503B of the FD&C Act. This draft guidance, when finalized, will describe FDA's expectations regarding outsourcing facilities and the CGMP requirements in 21 CFR parts 210 and 211 until more specific CGMP regulations for outsourcing facilities are promulgated. Under section 301(a) of the FDCA [21 U.S.C. § 331(a)], the introduction or delivery for introduction into interstate commerce of any drug that is adulterated is a prohibited act. Further, it is a prohibited act under section 301(k) of the FDCA [21 U.S.C. § 331(k)] to do any act with respect to a drug, if such act is done while the drug is held for sale after shipment in interstate commerce and results in the drug being adulterated	
FDA	Drugs	W	706206	At a minimum, you must use (b)(4) (refer to USP General Chapter (b)(4)) to manufacture your non-sterile drug products. (b)(4) must be suitable for its intended use and routinely tested to ensure ongoing conformance with appropriate chemical and microbiological attributes. You have not demonstrated that the (b)(4) is suitable for use and meets the USP (b)(4) monograph. 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	Food & Beverages	W	700600	2. You did not identify and evaluate a known or reasonably foreseeable hazard to determine whether it required a preventive control for your RTE bread products, as required by 21 CFR 117.130(a)(1). Specifically, your facility's written hazard analysis did not consider recontamination with environmental pathogens, such as Salmonella, at all steps where your RTE bread products are exposed to the environment. Though your hazard analysis determined that "(b)(4)" are a hazard requiring a preventive control at the (b)(4) steps for "(b)(4)" (finished product), it did not consider recontamination with environmental pathogens, such as Salmonella, as a known or reasonably foreseeable hazard at the (b)(4) step. Your facility manufactures RTE bread products (such as RTE Sliced Sourdough bread) which are exposed to the environment after baking and handled by employees prior to being packaged, such as during the (b)(4) step. The packaged food does not receive any further lethal treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize pathogens. Therefore, contamination with environmental pathogens is a known or reasonably foreseeable hazard. Furthermore, environmental monitoring is required if contamination of an RTE food with an environmental pathogen is a hazard requiring a preventive control (see 21 CFR 117.165(a)(3)). You were not performing environmental monitoring to evaluate the effectiveness of your sanitation practices. […] Furthermore, preventive controls are subject to preventive control management components (monitoring, verification, and corrective actions) as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control and its role in the facility's food safety system (see 21 CFR 117.140). We note that you did not have adequate controls in place for contamination with environmental pathogens regarding sanitation, monitoring, and verification activities, as evidenced by the following observations during the inspection on November 19, 2024:	
FDA	Food & Beverages	W	696743	2. You must have a HACCP plan that at a minimum, lists the critical limits that must be met, to comply with 21 CFR 123.6 (c)(3). A critical limit is defined in 21 CFR 123.3 (c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard. However, your firm's HACCP plan for "Dried Sliced Pollack" dated 2022-08-01 at the (b)(4) critical control point (CCP) lists a critical limit of "(b)(4)" that is not adequate to control pathogen growth and toxin formation including *Clostridium botulinum*. Because your RTE dried pollack is intended to be shelf-stable and is in reduced oxygen packaging your critical limit should ensure the finished product achieves a water activity of (b)(4) or less to control pathogens including *C. botulinum*. Additionally, because your (b)(4) temperature is (b)(4)°C ((b)(4)°F) which is in the temperature range for unrefrigerated processing (b)(4)°C ((b)(4)°F) and not a thermal process that will eliminate pathogens, the cumulative time exposure to temperatures in unrefrigerated processing should not exceed two hours to control pathogen growth and toxin formation other than *C. botulinum*. The cumulative time exposure for unrefrigerated processing would end once the product achieves (b)(4) or less water activity. The cumulative time for unrefrigerated processing should include additional processing steps that are performed at ambient air temperatures such as the rehydration, pressing, and tearing of pollack. Your critical limits should list the critical factors as established by a scientific study to achieve a water activity of (b)(4) or less in the finished product and for the water activity to be achieved within (b)(4) cumulative hours of unrefrigerated processing. Alternatively, if your (b)(4) temperature was increased to above (b)(4)°C ((b)(4)°F), then the (b)(4) process would not be considered unrefrigerated processing, and the cumulative time would not be restricted to (b)(4) hours.	
FDA	Drugs	W	707145	In response to this letter, provide: […] • An action plan and timelines for conducting microbiological testing of retain samples of all batches of drug product manufactured on (b)(4) and (b)(4) equipment distributed to the United States that are within expiry as of the date of this letter. […] See FDA's guidance document *Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice* to help you meet the CGMP requirements when manufacturing sterile drugs using aseptic processing at https://www.fda.gov/media/71026/download.	
FDA	Drugs	W	706567	1. Your firm failed to conduct, for each batch of drug product, appropriate laboratory testing, as necessary, required to be free of objectionable microorganisms (21 CFR 211.165(b)). You manufacture over-the-counter (OTC) drug products, such as antibacterial soaps. You failed to perform microbiological testing for your AllShield E2 Sanitizing Hand Soap. Batch records for lot 25009 indicated you did not take the required sample for microbiological testing, and quality assurance was unable to explain why the sample was not collected or the testing performed. Without testing each batch prior to release, you do not have scientific evidence that all drug product batches conform to the appropriate microbiological standards and are suitable for release to consumers. […] In response to this letter, provide: A list of chemical and microbial test methods and specifications used to analyze each lot of your drug products before making a lot disposition decision, and the associated written procedures. A comprehensive independent assessment of your laboratory practices, procedures, methods, equipment, documentation, and analyst competencies. Based on this review, provide a detailed plan to remediate and evaluate the effectiveness of your laboratory system. […] 3. Your firm failed to test samples of each component for identity and conformity with all appropriate written specifications for purity, strength, and quality (21 CFR 211.84(d)(1) and 211.84(d)(2)). You failed to perform adequate identity testing on your incoming components, including active ingredients, before using them in manufacturing your AllShield E2 Sanitizing Hand Soap. Additionally, you failed to ensure that microbiological testing was performed on your benzalkonium chloride solution API, which is required by the United States Pharmacopeia (USP) monograph. Without adequate testing, you do not have scientific evidence that the components conform to appropriate specifications prior to use in the manufacture of your drug products. 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.	

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