Date of This Update: May 1, 2024

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

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Product Type	Citation [C], Recall [R], Warning Letter [W]	Recall Details [R] FEI Number [C] MARCS-CMS [W]	Reason for Citation/Recall/Warning Letter
Biologics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=206478	Plateletpheresis product contaminated with Cutibacterium acnes, was distributed.
Devices	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=206502	There is a potential for sterile package breach.
Devices	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=206558	The positive control material (Rhizopus stolonifer) within the KWIK-STIK assembly was contaminated with another fungal organism (Aspergillus brasiliensis). As a result, users may observe A. brasiliensis growth when using the control material.
Devices	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=206457	The product does not meet sterility assurance level.
Devices	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=206380	Thermalon and MediBeads moist heat compresses from certain lots may have been exposed to excessive moisture, resulting in potential growth of mold and/or mildew.
Devices	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=206467	A new contraindication was added to the IFU which states that Peri-Guard Repair Patch should not be used in neurosurgery since the product endotoxin level may be higher than the allowable limit for cerebrospinal fluid-contacting devices and Supple Peri-Guard Repair Patch should not be used in neurosurgery since the product endotoxin level may be higher than the allowable limit for cerebrospinal fluid-contacting devices.
Devices	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=206596	A possible sterility issue (e.g. a breach in sterile packaging) was detected in Coloplast's facility on some ureteral dilator products. This issue on the ureteral dilator packaging has been identified during testing in our facility.
Devices	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=206552	Packaging may have low seal strength and not meet peel strength specifications, compromising device sterility
Devices	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=206597	Degraded and unusable upon removal from the foil pouch due to exposed environmental conditions during transit and storage, compromising sterility

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Devices	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=206737	The blood cultures performed as part of the organ donation process were positive for Staphylococcus aureus.
Drugs	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=204404	Lack of Assurance of Sterility
Drugs	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=206804	Lack of Assurance of Sterility: leaking bags
Drugs	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=206789	Lack of assurance of sterility: bags have the potential to leak..
Drugs	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=206556	Lack of Assurance of Sterility: Firm did not perform process validation.
Drugs	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=206942	Microbial contamination of a non-sterile product: potential Bacillus cereus contamination.
Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=206711	Salmonella contamination
Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=206258	Listeria monocytogenes. The recalled Cotija cheese was repackaged into finished wholesale and retail RTE products.
Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=205832	Listeria monocytogenes.
Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=206522	Potential contamination with Clostridium botulinum

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Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=206775	Possible salmonella contamination
Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=206944	The firm did not complete a hazard analysis for potential C. botulinum growth and toxin production of its processing, storage and shipping of raw onions into vacuum sealed bags.
Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=206393	Product may be contaminated with Salmonella.
Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=206790	L. mono contamination
Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=206915	Salmonella contamination
Veterinary	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=206422	Gerbil/hamster feed ingredient tested positive for Salmonella
Veterinary	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=206838	Sterility Assurance cannot be guaranteed for hand instruments.
Drugs	**C**	3002807834	Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.
Foods	**C**	3017212507	You did not conduct operations under conditions and controls necessary to minimize the potential for growth or survival of microorganisms and contamination of food.
Foods	**C**	1000307274	You did not conduct operations under conditions and controls necessary to minimize the potential for growth or survival of microorganisms, allergen cross-contact and contamination of food.
Veterinary Medicine	**C**	3002718478	You did not evaluate the raw materials and ingredients susceptible to contamination with mycotoxins or other natural toxins in a manner that does not result in animal food that can cause injury or illness to animals or humans.

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Drugs	**W**	MARCS-CMS 669170	"1. Your firm failed to test samples of each component for identity and conformity with all appropriate written specifications for purity, strength, and quality. Your firm also failed to validate and establish the reliability of your component supplier's test analyses at appropriate intervals (21 CFR 211.84(d)(1) and 211.84(d)(2)).1. Your firm failed to test samples of each component for identity and conformity with all appropriate written specifications for purity, strength, and quality. Your firm also failed to validate and establish the reliability of your component supplier's test analyses at appropriate intervals (21 CFR 211.84(d)(1) and 211.84(d)(2)). In response to this letter, provide: (…) 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 remediated system consistently produces water that meets (b)(4) Water, USP monograph specifications and appropriate microbial limits."
Drugs	**W**	MARCS-CMS 677928	"3. Your firm failed to establish and follow an adequate written testing program designed to assess the stability characteristics of drug products (21 CFR 211.166(a)). The records and information you provided did not demonstrate that your firm has an adequate stability program for the OTC hand sanitizer drug products that you manufacture. For example, your firm provided a stability test report which only include four weeks of stability data of (b)(4) batch of hand sanitizer. In addition, you failed to provide data demonstrating appropriate chemical and microbiological testing is performed on your drug products during your stability studies."
Drugs	**W**	MARCS-CMS 672903	"Inadequate Water System Your firm uses water as a component to manufacture your OTC drug products. You failed to adequately design your water system to ensure it was suitable for producing water used in the formulation of your drug products (i.e., multiple dead-legs, non-circulating loop) and to provide documentation of its qualification. You also failed to show that your water system is monitored adequately to ensure it consistently produces water that meets appropriate microbial limits. (b)(4) water must be suitable for its intended use and routinely tested to ensure ongoing conformance with appropriate chemical and microbiological attributes. Routine monitoring of microbial counts and identity of contamination in the system is integral to ensuring oversight of ongoing state of control and suitability of water for use in manufacturing operations. Your response regarding process validation and your water system is inadequate. You did not provide a detailed plan or supporting documentation for validating your drug production process or your water system. Further, you did not address the adequacy of your overall water system design to ensure your water meets quality attributes until the system consistently produces water meeting (b)(4) Water USP monograph specifications and appropriate microbial limits. You also failed to provide interim measures and assess the impact of using water from an unvalidated water system on the quality of drug products you manufacture. In response to this letter, provide: (…) A thorough remediation plan to install and operate a suitable water system. Include a robust ongoing control, maintenance, and monitoring program to ensure the remediated system design consistently produces water adhering to (b)(4) Water, USP monograph specifications, and appropriate microbial limits. 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."

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Drugs	**W**	MARCS-CMS 672956	"Your drug products are adulterated under section 501(a)(2)(A) of the FD&C Act because they were prepared, packed, or held under insanitary conditions. FDA investigators observed your facility to be in a state of disrepair, poorly cleaned and maintained as evidenced by: (b)(4) residue on the (b)(4) adjacent to the HEPA filters in the ISO 5 area. Multiple barefoot employees in an ISO 8 area, without required gowning, including gloves, while handling materials being transferred into the ISO 7 manufacturing area. Operators used visibly dirty restricted access barrier system (RABS) (b)(4) for interventions on the filling line. Your response is not adequate. While you commit to replacing the (b)(4) that surround the HEPA filtration system, your response does not include an evaluation of the residue on the (b)(4) to determine its identity or investigate the source. You also commit to perform re-training of personnel for gowning requirements and implement a procedure for sterilization of RABS (b)(4), however, you do not evaluate the microbiological impact that lack of proper gowning and unclean RABS (b)(4) has on your classified areas, such as ISO 5, ISO 7, and ISO 8. The potential impact to sterile drug products produced under these insanitary conditions is also not addressed. CGMP Violations 1. 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)). Poor Practices in the Aseptic Processing Areas In addition to the insanitary conditions described above, during the inspection of your facility, we observed poor practices and behaviors in ISO 5 areas during the manufacturing of sterile drug products. These poor practices included, but are not limited to: Operators performing interventions on the filling line in ISO 5 areas using a cloth to wipe the (b)(4) of the filling (b)(4) and the conveyor. Operators leaning over the filling line, including open and filled eye drop bottles, blocking unidirectional airflow. Operators in the ISO 5 area not wearing goggles and therefore had exposed skin during line set-up and aseptic processing. Operators observed placing bags of components that made contact with the walls in the ISO 7 area into the ISO 5 area without the bags being disinfected. Your response is inadequate because it does not address the lack of oversight for the operators' aseptic behaviors and if the initial training received was sufficient. Further, these poor aseptic practices were not investigated to determine the impact to sterile drug products and aseptic processing areas. Inadequate Media Fill Program Your media fills failed to accurately simulate commercial operations. Our inspection found the aseptic operations simulated during your media fills were not sufficiently representative of commercial aseptic manufacturing operations. It is your routine practice not to document interventions of the filling line in the manufacturing batch record during production. Because of this, your program lacks reliable data to determine the quantity and duration of interventions to simulate during media fills. In addition, during the inspection there were numerous interventions performed during routine manufacturing that were either not simulated as part of a media fill, or lacking in quantity and duration in the media fills compared to what was observed during production. Your response is inadequate. While you commit to document routine interventions during manufacturing, you fail to evaluate the interventions used in your media fill program and whether they represent routine production. Your operators performed numerous, manually intensive interventions during aseptic operations. As such, the quantity and duration of process simulation

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Drugs	**W**	MARCS-CMS 672462	"Adequate testing is essential to ensure that the drug products you manufacture conform to all pre-determined quality attributes that are appropriate for their intended use, including microbiological specifications. 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 product distributed to the United States that are within expiry as of the date of this letter."

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Food & Beverages	**W**	MARCS-CMS 656541	"A. Your hazard analysis considered "Presence of pathogenic bacteria" associated with your seeds and tree nut ingredients at your receiving step, but you determined that the hazard was not significant. However, vegetative pathogens such as Salmonella have been associated with these tree nuts and seeds food products. 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. The hazard may be controlled during your processing or at your supplier. Your process does not apply a process preventative control such as a lethal treatment to any of your incoming raw materials and ingredients used in production of your RTE nut and seed butters. Your manager stated that all tree nuts and seeds used to manufacture your RTE nut and seed butter products are received raw, but only your almonds and cashews receive a treatment at the supplier to reduce pathogens.. You told our investigators that your firm did not identify pathogens (pathogenic E. coli and/or Salmonella) as a significant hazard requiring a preventive control for tree nuts and seeds because these hazards can be controlled by your existing prerequisite programs as listed in your hazard analysis. These prerequisite programs include "Approved Supplier Program," "Good Manufacturing Practices" and "Receiving and Storage Practices." However, these written programs did not have procedures in place to verify that the supplier is controlling pathogens that may be present in raw materials to mitigate the hazard. Because you rely on your suppliers to control these hazards, the appropriate type of control is a supply-chain control. A facility that identifies raw materials and other ingredients with hazards such as Salmonella and E. coli 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 adequate supplier verification activities (see 21 CFR 117.410). Vegetative pathogens such as Salmonella in RTE tree nut and seed butters are hazards that can cause serious adverse health consequences or death. Therefore, an annual onsite audit is the appropriate supplier verification activity unless there is a written determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazard is controlled (see 21 CFR 117.430(b)). The audit must be conducted before using the raw material or other ingredient from the supplier and at least annually thereafter (see 21 CFR 117.430(b)(1)(ii)). D. Your hazard analysis included in your "Food Safety Plan for Nut and Seed Butters, Muesli, Bars, and oils Version 2" considered mycotoxins associated with your seeds and tree nuts as a potential food safety hazard to evaluate whether it requires a preventive control; however, you determined that the hazard was not significant based on ingredient and supplier history. Tree nuts and seeds are known to be associated with aflatoxins. Therefore, contamination with mycotoxins is a known or reasonable foreseeable hazard. A knowledgeable person manufacturing/processing food in your circumstances would identify mycotoxins as a hazard requiring a preventive control in these ingredients. We note that you have not established a preventive control within your facility to address mycotoxins. Therefore, you are required to establish and implement a supply-chain program covering mycotoxins in ingredients used to make your nuts and seed butters, to comply with 21 CFR 117.405(a)(1). You identified prerequisite programs such as "Approved Supplier Program" and "Receiving and Storage Practices" as programs in place to reduce chemical hazards. However, these programs did not indicate what procedures your firm has established to control mycotoxins, nor address verification activities or corrective actions. Moreover, you only receive certificates of analysis (COAs) for raw almonds, sesame seeds, and cashews, and they are not reviewed for mycotoxins. Your response dated March 31, 2023, stated that you reviewed and revised your risk analysis for all raw materials and process steps for all chemical hazards. Your revised hazard analysis for tree nuts does not identify mycotoxins as a significant hazard and states "[n]ot expected to occur, ingredient history indicates no instances of chemical contamination." However, we note mycotoxins are identified as a potential hazard at the receiving step and "Preventive Control (b)(4) – Approved Supplier Program which includes Continuing Letters of Guarantee and Specifications" is identified

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Food & Beverages	**W**	MARCS-CMS 668611	"1. You did not have and implement a written Salmonella Enteritidis (SE) Prevention Plan that includes, at minimum, the SE prevention measures, as required by 21 CFR 118.4. At the initiation of the current inspection, you indicated that you only have certain components of an SE Prevention Plan, but did not have a formal plan. Specifically: a. You did not have written procedures that procured pullets are SE-monitored or pullets are raised under SE-monitored conditions, as required by 21 CFR 118.4(a)(1), and that the pullet environment will be tested for SE when pullets are 14-16 weeks of age, as required by 21 CFR 118.4(a)(2). In your response, you provided an SE Prevention Plan describing the procurement of chicks from U.S. SE clean flocks and indicating that the pullet environment will be tested at 14-16 weeks; however, your plan indicates that your response to a positive SE test on the pullet farm would be to not accept the flock until a negative test is received. This is inadequate; if the pullet environment tests positive for SE, a producer must begin egg testing within two weeks of the start of egg production or divert eggs to treatment for the life of the flock, as required by 21 CFR 118.6(a)(1). We will verify the implementation and adequacy of your corrective actions during the next FDA inspection. 2. You failed to conduct environmental testing for SE, using approved methods, in a poultry house when any group of laying hens constituting the flock were 40 to 45 weeks of age, as required by 21 CFR 118.5(a). Specifically, you failed to conduct environmental testing for SE in the following poultry houses when any group of laying hens constituting the flock were 40 to 45 weeks of age: (…) In your response, you provided results from environmental samples collected from houses (b)(4) after the required time period for testing indicating that the houses were found negative for SE. You also provided your revised SE Prevention Plan which contains procedures for collecting environmental samples within your poultry houses. We will verify the implementation and adequacy of your corrective actions, including testing at the appropriate flock age intervals, during the next FDA inspection. In addition to the above violations, we offer the following comment: Your updated SE Prevention Plan indicates that you place environmental samples in (b)(4) with "(b)(4)". FDA's egg safety rule requires producers to follow "Environmental Sampling and Detection of Salmonella in Poultry Houses" April 2008 or an equivalent method in accuracy, precision, and sensitivity in detecting SE. Transporting samples in (b)(4) could potentially lead to inaccurate test results, and we encourage you to review your procedures to ensure that your collection and testing methodology is equivalent to FDA's egg safety rule requirements."
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NOVATEK INTERNATIONAL			https://ntint.com/
Rapidmicro biosystems®			https://www.rapidmicrobio.com
STERIS®			http://www.sterislifesciences.com/
vai VELTEK ASSOCIATES, INC.			http://www.sterile.com
rapid microbiology FOCUSED ON MICROBIOLOGY			https://www.rapidmicrobio.com
Giles Scientific, Inc.			https://www.biomic.com/trinity-v3.html
Special Process Services, LC			https://www.linkedin.com/in/joseph-connaghan-b663929
Becton Dickinson Integrated Diagnostic Solutions			https://www.bd.com/en-us/products-and-solutions/solutions/diagnostic-solutions