Date of This Update: April 6, 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

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Product Type	Citation [C], Recall [R], Warning Letter [WL]	Reason for Citation/Recall/Warning Letter
Biologics	**R**	elevated endotoxin levels in autologous platelet preparation kits
Biologics	**R**	Leukoreduced Apheresis Platelets, PAS, collected in a manner that compromises the sterility of the collection system, were distributed.
Biologics	**R**	Platelet products, for which the pathogen reduction process was not performed in accordance with specifications, were distributed.
Devices	**R**	Sterility; Sterile surgical procedure packs contain incomplete seals.
Drugs	**R**	Lack of assurance of sterility: Suspected microbial growth present on external label packaging.
Drugs	**R**	Non-Sterility: FDA analysis found unopened tubes to be contaminated with bacteria.
Drugs	**WL**	Firm must provide “The chemical and microbiological quality control specifications you use to test and release each incoming lot of component for use in manufacturing.” Cleaning validation studies were inadequate. “Additionally, you relied on certificates of analysis (COAs) from your suppliers to use incoming APIs without establishing the reliability of the specifications and characteristics of each supplier’s COAs.” Firm is to provide “ A description of how you will test each component lot for conformity with all appropriate specifications for identity, strength, quality, and purity. If you intend to accept any results from your supplier’s Certificates of Analysis (COA) instead of testing each component lot for strength, quality, and purity, specify how you will robustly establish the reliability of your supplier’s results through initial validation as well as periodic re-validation. In addition, include a commitment to always conduct at least one specific identity test for each incoming component lot.” Firm is to provide “A summary of results obtained from testing all components to evaluate the reliability of the COA from each component manufacturer. Include your standard operating procedure (SOP) that describes this COA validation program.” and: “A summary of your program for qualifying and overseeing contract facilities that test the drug products you manufacture.”
Drugs	**W**	Firm must provide "The chemical and microbiological quality control specifications you use to test and release each incoming lot of component for use in manufacturing." Water system problems: “You failed to establish adequate finished product testing procedures. You send finished product samples to a contract laboratory for microbial analysis. However, you have not adequately evaluated the suitability of the laboratory’s test methods for use with your drug products. In addition, you use an (b)(4) to quantify fluoride content as part of your finished drug products’ in-house testing. However, you lack sufficient evidence showing your method is equivalent or better than applicable USP compendial methods. For further information regarding the significance of Burkholderia cepacia complex and other objectionable contamination of non-sterile, water-based drug products, see FDA’s advisory notice posted on July 7, 2021, at https://www.fda.gov/Drugs/DrugSafety/ucm559508.htm." Contract manufacturers: “You are responsible for the quality of your drugs regardless of agreements in place with your contract facilities. You are required to ensure that drugs are made in accordance with section 501(a)(2)(B) of the FD&C Act to ensure safety, identity, strength, quality, and purity. See FDA’s guidance document Contract Manufacturing Arrangements for Drugs: Quality Agreements at https://www.fda.gov/media/86193/download."
Drugs	**WL**	Firm must provide: “ A list of chemical and microbial test methods and specifications used to analyze each lot of your drug product before making a lot disposition decision, and the associated written procedures.” and: “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.” Contract manufacturers: “You are responsible for the quality of your drugs regardless of agreements in place with your contract facilities. You are required to ensure that drugs are made in accordance with section 501(a)(2)(B) of the FD&C Act to ensure safety, identity, strength, quality, and purity. See FDA’s guidance document Contract Manufacturing Arrangements for Drugs: Quality Agreements at https://www.fda.gov/media/86193/download."

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Product Type	Citation [C], Recall [R], Warning Letter [WL]	Reason for Citation/Recall/Warning Letter
Food & Beverages	**WL**	"During our inspection of your facility, FDA investigators found serious violations of the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food regulation (CGMP & PC rule), Title 21, Code of Federal Regulations, Part 117 (21 CFR Part 117). During this inspection, FDA collected environmental samples (i.e., swabs) from various areas in your processing facility. FDA laboratory analysis of the environmental swabs found the presence of *Listeria monocytogenes* (*L. monocytogenes*), a human pathogen, in your facility." "Whole genome sequencing (WGS) was conducted on the above referenced *L. monocytogenes* isolates obtained from the FDA environmental samples, USDA/FSIS environmental samples, and FDACS product samples. Based on the results of the WGS analysis, these isolates represent eighteen (18) different strains of *L. monocytogenes*. The WGS analysis identified multiple strains of *L. monocytogenes* isolated over multiple years which is indicative of the presence of resident pathogens or harborage sites in your facility. We advised you of the WGS results and its importance on June 21, 2022. Of the eighteen (18) identified strains, the following nine (9) strains of are particular significance: One (1) strain includes isolates from FDA environmental samples collected from your facility in 2022, 2020, 2018, and 2017, the May 31, 2022 FDACS product sample of Ham Egg Cheese Sandwich which was manufactured at your facility, an environment sample collected from non-food contact surfaces at your facility in 2022 by USDA/FSIS, and environmental samples collected from other firm(s) located in Florida. One (1) strain includes an isolate from your Beef Beans Rice Cheese Burrito product sample collected by FDACS on May 31, 2022, which does not match any other food, environmental, or clinical isolates in the National Center for Biotechnology Information (NCBI) Pathogen Detection database. One (1) strain includes isolates from FDA environmental samples collected from your facility in 2017 and a 2015 FDACS product sample of Tuna Sandwich which was manufactured at your facility. One (1) strain includes isolates from an FDA environmental sample collected from your facility in 2017, a 2015 FDACS product sample of Ham Sandwich which was manufactured at your facility, an environment sample collected from non-food contact surfaces at your facility in 2015 by USDA/FSIS, an environmental sample collected from another of your sandwich manufacturing facilities (Charanga Catering, LLC located in Florida), and an environmental sample collected from one (1) firm located in Florida. One (1) strain includes isolates from FDA environmental samples collected from your facility in 2022, a 2015 FDACS product sample of Ham Omelet Sandwich which was manufactured at your facility, and environmental and product isolates collected from other firm(s) located in Florida. One (1) strain includes isolates from FDA environmental samples collected from your facility in 2018 and 2017, a 2015 FDACS product sample of a Midnight Regular Sandwich which was manufactured at your facility, and environmental and product samples collected from other firm(s) located in Florida. One (1) strain includes isolates from FDA environmental samples collected from your facility in 2017, 2015 FDACS product samples of a Deli Ham Sandwich and Ham Wrap Sandwich, which were manufactured at your facility, and environmental and product isolates collected from other firm(s) located in Florida. One (1) strain includes isolates from FDA environmental samples collected from your facility in 2022 and 2020, four (4) samples collected from ill people which were deposited in the public repository at the NCBI between 2014 and 2021, and UDSA/FSIS food and environmental isolates collected from firms located in Florida, Texas and New York. These findings demonstrate that this strain is known to cause human illness. One (1) strain includes isolates from an FDA environmental sample collected from your facility in 2022, a sample collected from an ill person which was deposited in the public repository at the NBCI in 2016 and food samples collected by USDA Agricultural Research Service. These findings demonstrate that this strain is known to cause human illness." "Given the history and current inspection findings, we continue to be concerned about your ability to maintain a sanitary environment. We recommend that you identify potential harborage sites and source(s) of the organism in your processing environment and implement the necessary methods and controls to ensure *L. monocytogenes* does not contaminate your environment or your RTE food products. Additionally, it would be beneficial if your firm has awareness for the sources of your incoming ingredients to ensure that potential routes of contamination could be mitigated. We will verify the effectiveness of your corrective actions and your ability to maintain a sanitary environment during our next inspection." "You did not hold food that can support the rapid growth of undesirable microorganism at temperatures that will prevent the food from being adulterated, as required by 21 CFR 117.80(c)(3). Specifically, your firm did not hold your RTE food products at adequate temperatures. Our investigators observed RTE food products being held in your customer sales area under ambient conditions for an extended period of time."

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Product Type	**Citation [C], Recall [R], Warning Letter [WL]**	**Reason for Citation/Recall/Warning Letter**
Food & Beverages	**WL**	"The presence of *L. monocytogenes* in your facility is significant in that it demonstrates your sanitation efforts are inadequate to effectively control pathogens in your facility to prevent contamination of food. Appropriate control of *L. monocytogenes* in a food processing environment requires knowledge of the unique characteristics of the organism and implementing the corresponding hygienic practices necessary to control this pathogen." "We note that your Cooler Temperature Control program did not include written procedures including monitoring, corrective actions, or verification activities for the temperature control of your cooler, which routinely stores RTE soft cheese products including Brie and Camembert. Also, during the inspection, our investigators observed that monitoring cooler temperature only occurred **(b)(4)** on weekdays and **(b)(4)** on weekends. Additionally, through record review during the inspection, we detected two (2) dates where temperatures were recorded as 51.2°F, 52°F and 53.1°F with no record of a corrective action documented. Soft cheeses can support the growth of pathogens, including *L. monocytogenes*, when not stored at proper refrigeration temperatures."

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Dietary Supplements	**WL**	"You use the (b)(4) Test Method to test your dietary supplement products for compliance with microbial specifications. This system includes testing for: Total aerobic plate count, procedure MICROSTP-001 Yeast and mold, procedure MICROSTP-002 Salmonella, procedure MICROSTP-003 Staphylococcus aureus, procedure MICROSTP-004 Escherichia coli, procedure MICROSTP-005 Enterobacteriaceae, procedure MICROSTP-006 However, you are not conducting suitability testing to demonstrate whether these methods are appropriate for testing all of your products. According to your (b)(4) Technical Report, dated April 8, 2019, you conducted suitability testing for ten products, but not for all products. The report also determined that two of the ten products, (b)(4), required modified preparation steps for neutralization, or else the test may not provide a valid result. The ingredients and amount of ingredients unique to individual dietary supplement products may interfere with the ability of microbial tests to provide a reliable result. Without suitability testing to demonstrate that a product does not interfere with the test, the method may not be determined to be an appropriate, scientifically valid method to verify that specifications are met." "Your firm's quality control personnel failed to conduct a material review and make a disposition decision when the established specification was not met, as required by 21 CFR 111.113(a)(1). Specifically, out of specification results were received for the following components and finished products:(b)(4) lot (b)(4), (b)(4) lot (b)(4), (b)(4) lot (b)(4) bulk softgels, (b)(4) raw material lot (b)(4), (b)(4) raw material lot (b)(4), and (b)(4) Suspension raw material lot (b)(4). For these components and finished products, your quality control unit failed to follow your procedure, "MICRO009: Laboratory Investigation of "Out of Specification" Results for Microbiological Testing," which outlines the appropriate steps when a microbial specification is not met during testing. Your procedure states, if laboratory testing results fail to meet the specification, "(b)(4)" and, "The (b)(4) (Attachment Ill)." You did not follow your procedure to conduct and document a laboratory investigation using Attachment Ill of your procedure; rather, you retested the samples until a passing result was obtained, and then reported the passing result without conducting an investigation for the initial failing results. No material review or disposition decision was performed by your firm in these examples where the dietary supplements or components failed to meet established specifications." "Our review of your (b)(4) system audit trail report noted multiple results for total microbial testing of your purified water system were above limit. No investigation was performed. You also failed to follow your SOP MICRO009 and SOP QA025 which require an out of specification (OOS) investigation to be initiated when obtaining out of limit microbial test and purified water results, respectively. Purified water is used as one of the components in your OTC drug products. In your response, you stated that your in-house testing was for information only and you sent the purified water samples to an outside testing laboratory for microbial release testing during the period of January 21, 2021, to July 9, 2021. You also stated that you suspended all internal microbiological laboratory operations until personnel and resources are in place to ensure compliance with all regulatory requirements. Your response is inadequate: Samples to your external laboratory were sent only after you obtained the in-house out of limit results. You lack evidence to support that a protocol was in place for the testing of your samples later claimed to be for information only. You failed to address the in-house test failures from September to November 2021. Your retrospective investigation was performed in March 2022, approximately one year after the first out of limit result was obtained. Your firm remains responsible for investigating all out of limit test results in a timely manner."
Food/Cosmetics	**R**	Contains B. cereus bacterium identified by the FDA in lab testing results.
Food/Cosmetics	**R**	[redacted], a producer of nutrition products, announced today that out of an abundance of caution, it has chosen to voluntarily recall two (2) select batches of ProSobee 12.9 oz. Simply Plant-Based Infant Formula due to a remote possibility of cross-contamination with Cronobacter sakazakii.
Food/Cosmetics	**R**	Potential mold (Cladosporium) contamination.

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Food/Cosmetics	**R**	Linden NJ 07036is initiating a recall of Enoki Mushroom, 200g, Plastic Bag, 25 bags per case because the product may be contaminated with Listeria monocytogenes.0
Foods	**C**	"You did not clean your non-food contact surface in a manner and as frequently as necessary to protect against contamination."
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