

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 is not intended to replace the information provided by the FDA, nor is it guaranteed to be complete. Text in the Reason for Citation/Recall/Warning Letter column is from the FDA. [compiled by David A. Porter, Ph.D.]

Product Type	Citation [C], Recall [R], Warning Letter [W]	Recall Details [R] FEI Number [C] MARCS-CMS [W]	Reason for Citation/Recall/Warning Letter
Food/Cosmetics	R	https://www.accessdata.fda.gov/scripts/ires/?Product=206307	Firm is recalling enchiladas made with Queso Fresno cheese due to the potential contamination with <i>Listeria monocytogenes</i> .
Food/Cosmetics	R	https://www.accessdata.fda.gov/scripts/ires/?Product=206234	Product has the potential to be contaminated with <i>Listeria monocytogenes</i> .
Devices	R	https://www.accessdata.fda.gov/scripts/ires/?Product=205839	Medical devices distributed, prior to sterilization
Food/Cosmetics	R	https://www.accessdata.fda.gov/scripts/ires/?Product=206233	L. mono contamination
Devices	R	https://www.accessdata.fda.gov/scripts/ires/?Product=206160	Potential packaging breaches of inner blister and outer sterile blister.
Biologics	R	https://www.accessdata.fda.gov/scripts/ires/?Product=206337	Blood Products, collected in a manner that compromises the sterility of the collection, were distributed.
Food/Cosmetics	R	https://www.accessdata.fda.gov/scripts/ires/?Product=206403	Product has the potential to be contaminated with <i>Listeria monocytogenes</i> .
Drugs	R	https://www.accessdata.fda.gov/scripts/ires/?Product=206531	Lack of assurance of sterility: pinholes, within the blue label characters on the EXCEL bag, specifically within the dotted characters on the label, resulting in leaks.
Drugs	R	https://www.accessdata.fda.gov/scripts/ires/?Product=206424	CGMP Deviations: Microbial contamination was reported in stagnant water in the duct of the manufacturing equipment.

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Drugs	R	https://www.accessdata.fda.gov/scripts/ires/?Product=206449	Lack of Assurance of Sterility: Out of specification for volume and compromised container closure.
Drugs	R	https://www.accessdata.fda.gov/scripts/ires/?Product=206445	Lack of Assurance of Sterility
Food/Cosmetics	R	https://www.accessdata.fda.gov/scripts/ires/?Product=206033	Possible listeria monocytogenes contamination
Food/Cosmetics	R	https://www.accessdata.fda.gov/scripts/ires/?Product=206023	Product ingredient may be contaminated with Listeria monocytogenes.
Devices	R	https://www.accessdata.fda.gov/scripts/ires/?Product=206176	Product failed sterility testing.
Food/Cosmetics	R	https://www.accessdata.fda.gov/scripts/ires/?Product=206018	L. mono contamination
Food/Cosmetics	R	https://www.accessdata.fda.gov/scripts/ires/?Product=206056	L. mono contamination
Food/Cosmetics	R	https://www.accessdata.fda.gov/scripts/ires/?Product=206050	Product has the potential to be contaminated with Listeria monocytogenes.

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Food & Beverages	W	<u>MARCS-CMS 676447</u>	<p>“1. Your HACCP plan does not include control measures that will consistently produce a 5-log reduction in the most resistant microorganism of public health significance that is likely to occur in the juice, for a period at least as long as the shelf life of the product, as required by 21 CFR 120.24(a).</p> <p>Specifically, Your HACCP / HARPC Plan Q2-2023 dated 25 April 2023 lists the following Critical Limits identified at the Pasteurization Critical Control Point (CCP) (b)(4) limit). You have defined Organic Carrot Juice as a Category III product with a (b)(4). The (b)(4) is not sufficient to inactivate the spores of Clostridium botulinum in carrot juice.</p> <p>You provided our investigator a challenge study entitled “(b)(4)” to support your critical limit and biological hazards identified for the Pasteurization CCP during the current inspection. Your written response included a justification which explained that “the current thermal processing eliminates all vegetative cells effectively.” Further, it explained “In the event of temperature abuse the growth of aerobic organism competitively prevents C. botulinum spore germination and growth, if present, and other undesirable biochemical changes cause the quality of the Carrot juice to degrade rapidly before the expiration date making the product undrinkable.”</p> <p>We reviewed your challenge study and written response and find them inadequate. The critical limits specified at the Pasteurization CCP (b)(4) is insufficient in ensuring control over any types of strains of C. botulinum, posing a serious risk to consumers due to the potential for spore growth and toxin production. (b)(4) for at least (b)(4).</p> <p>Your challenge study does not provide scientific rationale and sufficient data to demonstrate that C. botulinum is not a hazard in your carrot juice. Historical outbreak data demonstrates that C. botulinum is the pertinent microorganism in refrigerated carrot juice. Furthermore, the study does not support the shelf-life of the product which is defined as 28 days.”</p> <p>“2. Your HACCP plan does not list the critical control points for each of the identified food hazards that is reasonably likely to occur as required per 21 CFR 120.8(b)(2).</p> <p>Specifically, your HACCP / HARPC Plan Q2-2023 dated 25 April 2023 for fresh, refrigerated Organic Carrot Juice does not identify CCPs at labeling for maintaining product refrigeration, and of finished product refrigerated storage, to control the hazard of Clostridium botulinum growth and toxin formation in Organic Carrot Juice.</p> <p>As part of your written response, you provided a revised HACCP/HARPC Plan Q4-2023 for Processed Organic Carrot Juice which identifies Pasteurized Storage Tanks, Finished Food Storage and Labeling steps as critical control points for “biological.” The biological hazard is not defined to identify the pertinent microorganism of C. botulinum.</p> <p>Further, the current Juice HACCP Hazards and Controls Guidance, First Edition, states control measures for Low-acid juices, such as carrot juice “are likely to involve multiple measures, e.g., a combination of a process step to destroy the non-proteolytic spores and measures to ensure that “Keep Refrigerated” labeling is used for the juice if the juice does not receive a treatment sufficient to destroy the proteolytic spores.” As explained above, your pasteurization process is insufficient to destroy the non-proteolytic spores; therefore, these additional control measures alone do not adequately control the C. botulinum hazard.”</p> <p>“We are concerned about your lack of 5-log reduction in the most resistant microorganism of public health significance which has been identified as clostridium botulinum and the limited controls you have in place. “</p>
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			http://www.microbiologics.com
			https://ntint.com/
			https://www.rapidmicrobio.com
			http://www.sterislifesciences.com/
			http://www.sterile.com
			https://www.rapidmicrobio.com
Giles Scientific, Inc.			https://www.biomic.com/trinity-v3.html

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Special Process Services, LC			https://www.linkedin.com/in/joseph-connaghan-b663929