Date of This Update: March 15, 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
Animal and Veterinary	**W**	"You identified aflatoxins as a known or reasonably foreseeable hazard in some of your grain and grain co-product ingredients. However, you failed to identify aflatoxins as a hazard for cotton seed hulls and soy hull pellets, which are grains that are susceptible to aflatoxins."
Animal and Veterinary	**W**	"FDA laboratory analysis of the sampled pet food products revealed the presence of *Salmonella kentucky* and *Salmonella typhimurium* in FDA sample 1179788, and *Salmonella typhimurium* in FDA sample 1179789.***5*** Additionally, during the inspection of your facility, FDA collected a sample of your Natural Selections Antibiotic & Grain-Free Chicken Recipe for Cats, lot 9306 (FDA sample 1168289), and FDA laboratory analysis revealed the presence of *Salmonella typhimurium*." "FDA inspected your facility in June 2021, and subsequently sent you a letter dated August 27, 2021, documenting our concerns with your use of PAA as a pathogen mitigation step to reduce *E. coli* O157:H7 and *Salmonella* spp. in your raw pet food products. In our letter, we explained that any substances that may become part of your pet food, such as PAA, must be used as described in an animal food additive regulation, be generally recognized as safe (GRAS) for the intended use as defined by the FD&C Act, or should be otherwise not objectionable for use in animal food due to a definition in the AAFCO Official Publication."
Animal and Veterinary	**W**	"Specifically, your firm manufactures raw frozen and raw freeze-dried pet food and treats for dogs and cats. Your hazard analysis determined pathogens (*Salmonella* spp., *Listeria monocytogenes*, and E. coli O157:H7) are a hazard requiring a preventive control at the following steps: "Inbound Testing," "Mix Probiotics, Supplements, and Veggies," and "Outbound Testing." Your food safety plan identified the following preventive controls for the hazard of pathogens: "Supply Chain: Approved Supplier," "Probiotics," and "Outbound Micro Testing." During the inspection, your firm provided finished product microbial test results for cat and dog food manufactured between August 2021-August 2022 showing 49 products tested positive for *Listeria monocytogenes* or *Salmonella* spp. These positive results demonstrate the controls you have identified are not effectively and significantly minimizing or preventing the hazard of pathogens. An indication the controls you implemented are not adequate is that FDA laboratory analysis detected *Listeria monocytogenes* in an FDA surveillance sample (number 1146079) of your pet food, "Raw Frozen Primal Patties for Dogs Beef Formula," collected from retail on May 24, 2022, resulting in the July 6, 2022, Class I recall described above."
Biologics	**C**	"The phlebotomy site is not prepared by a method that gives maximum assurance of a sterile container of Whole Blood."
Devices	**R**	The convenience trays had improper placement of some of the components that were in the nonsterile portion of the tray, thus, not receiving sterilization.
Devices	**R**	Sterile product pouches were not sealed.
Devices	**R**	Sterile Barrier Breach of Breather Pouch may cause infection or vision loss for ophthalmic procedures in cases where there is direct patient contact
Devices	**R**	Firm has initiated a removal of the product due to insufficient evidence of packaging sterility. Exposure to a non-sterile medical device may result in inflammation, infection, sepsis, or ischemia.
Devices	**R**	Device packaging may contain open seals, compromising product sterility.
Devices	**R**	For users with MYLA V4.8.X / V4.9 that use VITEK MS to identify organisms as part of their workflow, AST filter rules that have been activated are not always being applied to AST results when sending the results to the clinician.
Devices	**R**	MiniCap Disconnect Cap with Povidone-Iodine are packaged in foil pouches, which may have been incorrectly sealed, i.e., the pouches may have open or weak seals. This could lead to exposure to air, resulting in insufficient iodine/dry sponge inside the MiniCap, which could lead to the potential for inadequate disinfectant.
Devices	**R**	Affected lots have the potential for a broken sled vane, which may cause the reload to misfire leading to non-functional staple line closure, transecting tissue without forming staples, and tissue hang-up. These conditions may be associated to a delay to treatment, unspecified infection, hemorrhage/blood loss/bleeding, failure to anastomose, peritonitis, sepsis, pneumothorax, tissue trauma, or death.
Devices	**R**	Nonsterile syringe potentially exposing the patient to pathogenic microorganisms and a risk of local infection.
Drugs	**R**	Lack of sterility assurance: Recall of certain batches of 0.9% Sodium Chloride for Injection USP in EXCEL¿ Plus IV Container product due to the possibility of an incomplete seal that may cause leakage. The impacted lots may exhibit microscopic channel leaks near the port assembly of the product.

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Drugs	**R**	Lack of Assurance of Sterility
Drugs	**R**	Lack of sterility assurance: Cracks have developed in some of the units caps of Brimonidine tartrate ophthalmic solution bottles. There is a possibility the broken cap may impact sterility.
Drugs	**R**	Non-Sterility
Drugs	**W**	"Your firm uses water from your water system as a component to manufacture your drug products, however, you lack validation studies for your water system. Your firm has not demonstrated that you can effectively design, control, maintain, and monitor the system, so it consistently produces pharmaceutical grade water that, at a minimum, meets the USP monograph for **(b)(4)** water and appropriate microbial limits."
Drugs	**W**	"You failed to perform analytical and microbiological release testing for each batch of your over-the-counter (OTC) topical drug products prior to distribution, including Xpasmo Manteca de Ubre (Cow's Udder grease) and Xpasmo Arthritis Formula."
Drugs	**W**	"1. 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, and for each batch of drug product required to be free of objectionable microorganisms, appropriate laboratory testing, as necessary (21 CFR 211.165(a) and (b))"
Drugs	**W**	"2. 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))." "Your firm released and distributed OTC drug products without adequate finished product testing. For example, you performed limited release testing (temperature, odor, appearance, and alcohol concentration) as part of the production record. However, full release testing, including identity, strength, quality, and purity must be performed before drug release and distribution, as required under 21 CFR 211.165(a). You also released finished drug products without testing for critical microbial attributes, such as testing to ensure absence of objectionable microorganisms, as required under 21 CFR 211.165(b)."
Drugs	**W**	"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)). Your firm failed to adequately test your over-the-counter (OTC) drug products prior to release for distribution. For example, although your batch records for hand sanitizer1 and antibacterial hand soap drug products include a requirement for microbial testing, you failed to test each batch for microbial attributes. Instead, you told our investigator that you only send (b)(4) to a third-party laboratory for analysis. You also did not provide documentation of what was included in the referenced standard plate count testing when requested by investigator or a scientific rationale for the sample testing frequency."
Foods	**C**	"You did not conduct operations under conditions and controls necessary to minimize the potential for growth or survival of microorganisms and deterioration of food."
Foods	**C**	"Your written environmental monitoring plan does not list a sufficient number of sampling sites to determine whether measures are effective."
Foods	**C**	"You did not discontinue the use of all from a lot for which you know or have reason to believe that the were contaminated with a pathogen."
Foods	**C**	"You did not conduct operations under conditions and controls necessary to minimize the potential for growth or survival of microorganisms and allergen cross-contact."

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Food & Beverages	**W**	"You failed to perform analytical and microbiological release testing for each batch of your over-the-counter (OTC) topical drug products prior to distribution, including Xpasmo Manteca de Ubre (Cow's Udder grease) and Xpasmo Arthritis Formula." "b) You did not identify and evaluate bacterial growth and/or toxin formation due to lack of time/temperature control as a known or reasonably foreseeable hazard to determine whether they are a hazard requiring a preventive control. Your facility hot-packs your RTE hummus (e.g.,**(b)(4)**) in five-pound (5 lb.) plastic tubs, which are **(b)(4)**sealed with film, covered with plastic lids, and given a two-month shelf life (i.e., **(b)(4)** packaging). You then place the 5 lb. tubs of hummus in your walk-in cooler for cooling and finished product storage. Some of your hummus ingredients have been associated with pathogens (e.g., *Salmonella* in **(b)(4)**, and *Clostridium botulinum* in **(b)(4)**). Vegetative and sporeforming pathogens (i.e., that survive the cook step or are introduced after cooking) which are not cooled properly or otherwise time-temperature abused could grow (and produce toxins if applicable). Specifically, your RTE hummus is packed in **(b)(4)** conditions, and *Clostridium botulinum* is an anaerobic bacterium which can grow and produce toxin in **(b)(4)** conditions. A knowledgeable person manufacturing/processing food in your circumstances would identify bacterial growth and/or toxin formation due to lack of time/temperature control as a hazard requiring a preventive control. Process controls include procedures, practices, and processes to ensure the control of parameters during operations such as refrigerating foods. Process controls must also include the parameters associated with the control of the hazard and the minimum and maximum values needed to significantly minimize or prevent the hazards (see 21 CFR § 117.135(c)(1))." "d) You did not identify and evaluate contamination with environmental pathogens, such as *Salmonella*, as a known or reasonably foreseeable hazard to determine whether it is hazard requiring a preventive control, to comply with 21 CFR § 117.130(c)(1)(ii). Your facility manufactures RTE hummus (e.g., **(b)(4)**) which is exposed to the environment after cooking prior to packaging. Your employees hand-pack the food and 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 the pathogen. A knowledgeable person manufacturing/processing food in your circumstances would identify contamination with environmental pathogens as a hazard requiring a preventive control. Sanitation controls include procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as environmental pathogens and biological hazards due to employee handling (see 21 CFR § 117.135(c)(3)). In addition, 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)). Note that if environmental monitoring is required, an environmental monitoring written procedure must be established and implemented and must meet the requirements in 21 CFR § 117.165(b)(3)." "v. During the inspection, FDA investigators found that you perform periodic environmental swabbing of **(b)(4)** and that you conduct that swabbing about **(b)(4)**. Environmental swabbing is intended to be a verification of the implementation and effectiveness of your sanitation preventive controls and the locations, frequency, and timing of the sampling is critical to determining that effectiveness. Moreover, FDA detected non-pathogenic *Listeria species (Listeria spp.)*, in environmental samples collected from your facility. Specifically, FDA laboratory analysis of the environmental sample 1194658 collected on July 11, 2022 confirmed one (1) *Listeria spp*. positive swab collected from the floor near the wire slicer. The presence of non-pathogenic species of *Listeria* indicates that conditions are suitable for survival and/or growth of *L. monocytogenes* in the locations where they are found."
Food & Beverages	**W**	"a) You did not visually check the data generated by a temperature recording device during transit at your receiving critical control point (CCP) to control the listed hazards of C. botulinum toxin and histamine formation."
Food/Cosmetics	**R**	Similar finding are also noted.
Food/Cosmetics	**R**	The recalled product did not meet the pre-kill step processing specifications and has the potential to be spoiled.
Food/Cosmetics	**R**	Hand soaps potentially contaminated with pseudomonas
Food/Cosmetics	**R**	Product was found to have an elevated amount of Aflatoxin
Food/Cosmetics	**R**	Product was not properly labeled in English for importing into the US and filth was found in product (including mold, hair, bird feather, yarn).
Food/Cosmetics	**R**	On 02/03/2023, [redacted] is initiating a recall of various products sold from January 24, 2023 through January 30, 2023 because the products have the potential to be contaminated with Listeria monocytogenes .
Food/Cosmetics	**R**	Possible contamination with Listeria monocytogenes.
Food/Cosmetics	**R**	Product found to contain Listeria monocytogenes

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