Date of This Update: March 6, 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
Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=205515	The underlying ingredient, shredded lettuce, was recalled by the supplier Fresh Express due to potential contamination with Listeria monocytogenes.
Veterinary	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=204346	Positive Salmonella Sample
Veterinary	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=205005	The firm was notified by North Carolina Department of Agriculture and Consumer Services that the products tested positive for Salmonella and Listeria.
Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=205420	Possible contamination with Listeria monocytogenes
Drugs	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=205575	CGMP Deviations: Microbial contamination was reported in stagnant water in the duct of the manufacturing equipment.
Drugs	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=205355	Lack of Sterility Assurance: Aseptic process simulation failure.
Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=205307	Potential L. mono contamination as a result of FDA environmental sampling revealing positive findings.
Veterinary	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=205154	Salmonella contamination via FDA test, sample 1233757
Veterinary	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=204018	Positive Salmonella sample

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Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=205309	Product has the potential to be contaminated with Cronobacter sakazakii.
Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=205709	The food was not held at an appropriate temperature. The holding temperature could affect spoilage and potentially support pathogen growth.
Drugs	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=204553	Non-Sterility
Devices	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=205598	Failed to meet the acceptance criteria for the seal integrity and/or package integrity testing for the Sterile Barrier Outer Pouch and the Protective Barrier Inner Pouch, compromising product sterility
Devices	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=205349	Sterile-packed Cranial Drills may not be sterile due to a breach in the packaging and/or may have discoloration near the drill tip.
Devices	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=205313	Packaging of the device may cause a low seal strength in the side seal of the foil pouch potentially resulting in a sterile/moisture barrier breach, compromising the product sterility
Devices	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=205465	Devices may not be rendered sterile due to an internal gap that may be present on some devices causing increased difficulty cleaning prior to steam sterilization. There is an increased risk for infection, inflammation, local toxicity, systemic toxicity, sensitivity, and cross-contamination.
Devices	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=205621	Water filter may have been assembled incorrectly, resulting in unfiltered tap water being used for reprocessing. This may expose a patient to a potentially contaminated device, presenting a risk of infection or sepsis.
Drugs	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=205174	Microbial Contamination of Non-Sterile Products
Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=206037	Product has the potential to be contaminated with Listeria monocytogenes. The condiment pack in the salad kit contains cheese recalled by the cheese supplier.

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Drugs	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=206035	Potential presence of Burkholderia cepacia complex (BCC)
Devices	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=205489	Sterility assurance for saline included in surgical kits cannot be guaranteed.
Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=206102	Product was made with a lack of proper pasteurization.
Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=206071	Listeria monocytogenes. The recalled Cotija cheese was repackaged into finished RTE Sprig and Sprout Ham and Cotija Torta Sandwich on Telera Roll.
Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=206144	Listeria monocytogenes contamination.
Devices	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=205734	Medline Industries, LP is recalling certain kits and trays that were manufactured using specific lots of Nurse Assist (as components): 0.9% Sodium Chloride Irrigation USP, Sterile Water for Irrigation USP and Saline Flush Syringe. Nurse Assist issued a recall due to the potential lack of sterility, which could result in the solution being non sterile.
Veterinary	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=205747	FDA notified the firm that via our Adverse Event Reporting system that a positive test results for Listeria monocytogenes and Salmonella was found in the product.
Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=205943	potential Salmonella
Drugs	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=205784	Lack of Assurance of Sterility
Devices	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=205793	A defect in the sterile packaging (header bag) of the Cranial Access Kit failing the required packaging integrity testing criteria. Therefore, product sterility maybe compromised.

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Biologics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=206135	Fenwal International, Inc. (a Fresenius Kabi Company) is initiating a voluntary recall for certain lots of Fenwal Blood-Pack Unit product codes due to an elevated presence of bacteria that was found in pre-sterilization in-process testing during the manufacture of certain BPU lots in late 2022 and early 2023. This deviation raises the possibility of the following: transfusion of a patient with blood product(s) contaminated with viable bacteria or elevated levels of endotoxin, the Sterility Assurance Level (SAL) Hazard would lead to a released batch which would not meet a SAL of 10-6, and/or the resulting product may be out of specification for endotoxins.
Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=206044	Product has the potential to be contaminated with Listeria monocytogenes.
Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=206136	Listeria monocytogenes
Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=206001	Potential contamination of Listeria monocytogenes
Devices	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=205920	Products not sterilized, sterility cannot be confirmed
Devices	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=205717	The sterile blister packaging may be damaged, and sterility may be compromised.
Foods	**C**	2128750	A system for processing a low-acid food in hermetically sealed containers was not operated and administered in a manner adequate to ensure that commercial sterility was achieved.
Veterinary Medicine	**C**	3011216164	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.
Drugs	**W**	MARCS-CMS 667057	3. Your firm failed to establish an adequate quality unit and the responsibilities and procedures applicable to the quality control unit are not in writing and fully followed (21 CFR 211.22(a) and 211.22(d)). 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. 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.

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Biologics	**W**	MARCS-CMS 662942	3. In-process control procedures are deficient in that your control procedures do not include bioburden testing [21 CFR 211.110(a)(6)]. According to your Process Performance Qualification Report for Placental Collagen Matrix (PCM) (effective 2/20/23), your firm removed (b)(4) bioburden testing from routine commercial production of AXIOFILL™ after completing "validation production." Your product is (b)(4) sterilized. In-process bioburden testing is critical for assuring that bioburden levels do not exceed the validated sterility assurance level (SAL). Additionally, with respect to your final specifications used for testing and release of AXIOFILL™, we have concerns that your firm has failed to include specifications for elemental impurities and endotoxin, although your firm has identified "elemental impurities from product surfaces" and endotoxin as critical quality attributes in your Process Performance Qualification Report for Placental Collagen Matrix (PCM) (effective 2/20/23). We are also concerned that your firm did not provide a disinfectant efficacy study for (b)(4), used in your processing facility and on production equipment, during the inspection, although it was requested. Neither this letter nor the observations noted on the FDA-483, which were discussed with you at the conclusion of the inspection, are intended to be an all-inclusive list of deficiencies that may exist at your facility. It is your responsibility to ensure full compliance with the FD&C Act, PHS Act, and all applicable regulations.
Drugs	**W**	MARCS-CMS 669486	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 (21 CFR 211.165(a)). In response to this letter, provide: A list of chemical and microbial specifications, including adequate 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. In response to this letter, provide: The chemical and microbiological quality control specifications you use to test and release each incoming lot of component for use in manufacturing.

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Food & Beverages	**W**	MARCS-CMS 663904	The inspection revealed 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). Your significant violations are as follows: 1. You did not have and implement a written Salmonella Enteritidis (SE) Prevention Plan that includes, at minimum, the SE prevention measures required by 21 CFR118.4. You have a document titled “SE Prevention Plan”; however, as describedbelow, this plan is inadequate in that it does not address all required SE prevention measures. Cleaning and Disinfection Your SE Prevention Plan did not include cleaning and disinfection procedures for poultry houses, in the event that you have an environment test or egg test that was positive for SE at any point during the life of a flock, as required by 21 CFR 118.4(d). 2. You did not hold or transport eggs at or below 45°F ambient temperature beginning36 hours after the time of lay, as required by 21 CFR 118.4(e). Your SE Prevention Plan stated “eggs should be stored in a cooler that is (b)(4)”; however, your cooler temperatures routinely exceeded 45°F. For example, from May 4, 2023, through June 4, 2023, the documented cooler temperatures ranged from 51°F to 68°Fconsecutively for 31 days. 3. You did not conduct environmental testing for SE in your poultry houses when laying hens were 40 to 45 weeks of age, as required by 21 CFR 118.5(a). Specifically, the (b)(4) house and the (b)(4) house were tested when the flocks were approximately 48 weeks of age. Further, we have concerns regarding your handling of environmental samples. For example, the laboratory record dated March 3, 2023, indicates the sample receipt date as March 1, 2023. However, this record also indicates that the (b)(4) house was sampled on February 27, 2023, with the date “on the bag” indicated as February25, 2023. Additionally, this laboratory record indicates that (b)(4) house was sampled on February 26, 2023, but indicates the date “on the bag” as February 14,2023. No further explanation was provided to clarify the testing timeframes and date submitted to the laboratory for analysis. In addition to the following violations, we also offer the following comments: 1) Inspectors observed many uncaged birds running around the floor of the belted house. Farm management indicated that these birds would be caught and placed back in designated cages with no particular frequency. Not returning birds to cages with sufficient frequency creates the potential for further spread and cross-contamination of SE within a flock and farm if your poultry house were to be SE positive. You should manage loose birds on a daily basis, in addition to disposing of dead birds, spilled feed, manure, and refuse.

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Drugs	**W**	MARCS-CMS 675685	1. You did not perform adequate product evaluation and take appropriate corrective actions after mold was recovered on operator glove finger plate samples taken after aseptic operations within the ISO 5 area. 1. An operator placing their upper left side of their body into the ISO 5 hood within the syringe filler. In addition, another operator was observed placing their sleeves, chest, and forehead under the ISO 5 hood. 2. Your firm failed to 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)). 3. Your firm failed to establish an adequate system for monitoring environmental conditions in aseptic processing areas (21 CFR 211.42(c)(10)(iv)).

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Drugs	**W**	MARCS-CMS 658390	Pseudomonas aeruginosa Outbreak and FDA Testing of Samples In December 2022, FDA began collaborating with the Center for Disease Control and Prevention (CDC) on an investigation into the multistate outbreak of antibiotic-resistant Pseudomonas aeruginosa infections that ultimately affected more than 80 patients and led to 4 patient deaths and at least 14 cases of vision loss. As part of this investigation, FDA collected finished product samples of Artificial Tears batches that were manufactured for EzriCare LLC by Global Pharma Healthcare Private Limited, and we sent the samples for sterility testing at FDA laboratories. Our analysis of intact (unopened) units found that 14 batches of EzriCare LLC's Artificial Tears were non-sterile. The testing of these intact units revealed that your ophthalmic drug products were intrinsically contaminated with microorganisms. Microbiological isolates from the non-sterile samples were further characterized using whole genome sequencing and compared to isolates in a national database.2Pseudomonas aeruginosa isolates from three different batches of intact Artificial Tears samples collected by FDA were found to be close genetic matches to more than 85 clinical isolates associated with this outbreak. These test results demonstrate that these batches are adulterated under section 501(a)(1) of the FD&C Act, in that they consist in whole or in part of a filthy, putrid, or decomposed substance. Significantly, the contamination of the drug products manufactured at Global Pharma Healthcare Private Limited, as indicated by FDA sample results, also demonstrates that the drugs made for you at Global Pharma Healthcare Private Limited are adulterated under 501(a)(2)(A) of the FD&C Act as they have been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health. In addition, two intact samples of EzriCare's Artificial Tears from different batches were found to contain visible, foreign particles. Inspection of your CMO An inspection of Global Pharma Healthcare Private Limited, conducted from February 20 to March 2, 2023, revealed multiple CGMP violations, including but not limited to, the use of filling equipment that was inadequate for its intended use; the failure to validate the sterilization processes used to render ophthalmic drug products sterile; the lack of container closure integrity for multidose ophthalmic drugs that purport to be sterile; and the manufacture of multidose, over-the-counter (OTC) ophthalmic drugs that lack antimicrobial properties to preserve the formulation. Global Pharma Healthcare Private Limited was placed on Import Alert 66-40 on January 3, 2023, and received a Warning Letter (WL# 320-24-03), dated October 20, 2023, documenting the egregious CGMP violations. FDA sent you a copy of the warning letter issued to Global Pharma Healthcare Private Limited. Inspection of EzriCare LLC During our inspection of your facility, you confirmed that you utilized CMOs to manufacture and import your ophthalmic drug product; however, you failed to have adequate procedures to ensure the ophthalmic drug products produced for your firm met appropriate quality attributes and were free of microbial contamination. For example, you failed to have adequate supplier qualification procedures to ensure that the drug products received from Global Pharma Healthcare Private Limited were manufactured in compliance with CGMPs prior to being distributed in the United States. Additionally, you were unable to provide any written agreements or procedures that demonstrated you required your CMOs to meet CGMP requirements or make suitable release decisions of drug products for distribution into the U.S. supply chain. You stated in your response that your supplier, (b)(4), was responsible for the "formulation, packaging, and labeling" of the drug products that you distribute, however, your multidose ophthalmic drug product, labeled as EzriCare Artificial Tears, did not include a preservative, which in part rendered it injurious to health. You also stated that (b)(4) denied you direct contact "on multiple occasions" with your own CMO, yet you continued to distribute these drug products.

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Drugs	**W**	MARCS-CMS 657340	Pseudomonas aeruginosa Outbreak and FDA Testing of Samples In December 2022, FDA began collaborating with the Center for Disease Control and Prevention (CDC) on an investigation into the multistate outbreak of antibiotic-resistant Pseudomonas aeruginosa infections that ultimately affected more than 80 patients and led to 4 patient deaths and at least 14 cases of vision loss. As part of this investigation, FDA collected finished product samples of Artificial Tears and Artificial Eye Ointment batches that were manufactured for Delsam Pharma LLC by Global Pharma Healthcare Private Limited, and we sent the samples for sterility testing at FDA laboratories. Our analysis of intact (unopened) units found that four batches of Delsam Pharma's Artificial Tears were non-sterile.2 In addition, we also sampled a batch of your Artificial Eye Ointment product, and this batch was also found to be non-sterile. The testing of these intact units revealed that your ophthalmic drug products were intrinsically contaminated with microorganisms. These test results demonstrate that these batches are adulterated under section 501(a)(1) of the FD&C Act, in that they consist in whole or in part of a filthy, putrid, or decomposed substance. FDA's laboratory also performed container closure integrity testing of Delsam Pharma's Artificial Eye Ointment, batch (b)(4), manufactured for your firm. FDA tested 20 units, and 1 unit was found to allow microbiological ingress, which confirmed that your container-closure system lacks integrity and is insufficient for maintaining sterility. Notably, batch (b)(4) was also found to be non-sterile through FDA testing. Inspection of your CMO An inspection of Global Pharma Healthcare Private Limited, conducted from February 20 to March 2, 2023, revealed multiple CGMP violations, including but not limited to, the use of filling equipment that was inadequate for its intended use; the failure to validate the sterilization processes used to render ophthalmic drug products sterile; the lack of container closure integrity for multidose ophthalmic drugs that purport to be sterile; and the manufacture of multidose, over-the-counter (OTC) ophthalmic drugs that lack antimicrobial properties to preserve the formulation. Global Pharma Healthcare Private Limited was placed on Import Alert 66-40 on January 3, 2023, and received a Warning Letter (WL# 320-24-03), dated October 20, 2023, documenting the egregious CGMP violations. FDA sent you a copy of the warning letter issued to Global Pharma Healthcare Private Limited. Inspection of Delsam Pharma LLC Your firm utilized a CMO to manufacture your ophthalmic drug products; however, your firm failed to have adequate procedures to ensure that all ophthalmic drug products produced for your firm met appropriate quality attributes and were free of microbial contamination. You also failed to have adequate supplier qualification procedures to ensure that the drug products received from Global Pharma Healthcare Private Limited were manufactured in compliance with CGMP prior to being distributed in the United States. Use of Contract Manufacturers Drugs must be manufactured in conformance with CGMP. FDA is aware that many drug manufacturers use independent contractors such as production facilities, testing laboratories, packagers, and labelers. FDA regards contractors as extensions of the manufacturer. You are responsible for the quality of your drugs regardless of agreements in place with your contract facility. You are required to ensure that the drugs you distribute are not adulterated. See FDA's guidance document Contract Manufacturing Arrangements for Drugs: Quality Agreements at https://www.fda.gov/media/86193/download.

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Drugs	**W**	MARCS-CMS 665450	FDA laboratory testing of MSM Eye Repair Drops, batch "P15D7 April 11th 2023" obtained directly from your LightEyez website found gross microbial contamination. Microbiological testing of ten composite samples (i.e., two individual samples per composite) were analyzed. All ten composite samples found gross microbial growth. These test results demonstrate that this ophthalmic drug product is adulterated under section 501(a)(1) of the FD&C Act, in that it consists in whole or in part of a filthy, putrid, or decomposed substance. Examples of microbial contaminants found in your product include Pseudomonas spp., Mycobacterium spp., Mycolicibacterium spp., and Methylorubrum spp. The presence of microorganisms in conjunction with the route of administration poses a high risk to patients. Using contaminated eye drops could result in a range of ocular infections, from minor to serious vision-threatening infections which could progress in some cases to a life-threatening infection. On August 22, 2023, FDA issued a drug safety alert warning consumers not to purchase or use certain methylsulfonylmethane (MSM) eye drops, including your MSM Eye Repair Drops, due to bacterial contamination, as noted on the following FDA website: https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-consumers-not-purchase-or-use-certain-methylsulfonylmethane-msm-eye-drops-due On August 24, 2023, the FDA held a teleconference with your legal representative located in the United Kingdom (U.K.) regarding your MSM Eye Repair Drops. During the call, your representative stated that your firm supplies your U.S. manufacturer (b)(4) with drug components to conduct further manufacturing of your ophthalmic drug product. Your firm agreed to voluntarily recall your sterile drug products in U.S. distribution and that your U.S. manufacturer (b)(4) would process the voluntary recall of your ophthalmic drug products. On August 25, 2023, your U.S. manufacturer (b)(4), located in Sarasota, Florida, responded to FDA and confirmed drug components used in your MSM Eye Repair Drops were imported from LightEyez (U.K.). The drug components imported included methylsulfonylmethane (MSM) used as an active ingredient in your ophthalmic drug product. (b)(4) also indicated that a malfunctioning water system resulted in the use of unfiltered municipal water in your ophthalmic drug product. Based on our review of your firm's website at https://www.lighteyez.com/neweyecolorsupport.html, we have concerns regarding whether your container closure system will provide adequate protection against foreseeable external factors. Your website provides consumers with instructions on how to clear blockages of your container closure dropper tip intended for your ophthalmic drug products. Your recommendations instruct consumers to insert a foreign object into the dropper tip nozzle and/or remove the dropper tip to clear a blockage, which risks contamination of your ophthalmic drug products with foreign particulate matter and/or microorganisms.

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Drugs	**W**	MARCS-CMS 668867	1. Your firm failed to perform operations within specifically defined areas of adequate size and to have separate or defined areas or such other control systems necessary to prevent contamination or mix-ups in aseptic processing areas (21 CFR 211.42(c)(10)). Inadequate Design of Facility and Equipment Your firm is a contract manufacturer of sterile over-the-counter (OTC) and homeopathic (b)(4) drug products produced by aseptic processing. You described your aseptic processing lines as "filling lines encompassed (b)(4), surrounded by (b)(4). Your processing lines, as designed, required manually intensive operations during equipment setup and throughout routine production, and did not provide acceptable protection of the ISO 5 area. For example, we observed fundamental design flaws including, but not limited to: Excessive and high-risk manual interventions during batch manufacture. The number and nature of interventions performed on your aseptic processing lines included unacceptable risks to product sterility. For instance, a batch produced on (b)(4) in July 2023 required several hundred manual interventions. Product contact equipment on multiple lines were exposed to poorly protected and unacceptable conditions. Some examples: o Interventions included periods of time that (b)(4) near the (b)(4) remained (b)(4) exposing product for approximately 3 minutes. o The (b)(4) hopper lacked an adequate cover and was substantially exposed to the surrounding environment. o The (b)(4) hopper on (b)(4) extended from ISO 5 (Grade A) into the ISO 7 (Grade B) environment, and made contact with bending (b)(4) from the latter, lower classified environment. Aseptic connections were excessive, included breaches in aseptic technique, and were performed under unacceptable air classifications. o For instance, when performing aseptic assembly connections of sterile tubing on the (b)(4) line, this poorly designed connection involved manipulations in which sterile (b)(4) tubing entered into ISO 7 environments and contacted non-sterile surfaces during manipulations by operators. In addition, multiple small pieces of tubing were serially aseptically connected to reach the filling equipment, with significant contamination hazard posed by each of these successive interim connections. Your firm stated that only small sections of tubing could be sterilized because your (b)(4) was not of suitable size to accommodate sterilization of longer tubing. Equipment was not consistently designed with appropriate, smooth surfaces to facilitate cleaning and disinfection. For instance, we observed a hopper fixture with exposed screw threads and hinges on (b)(4). Set-up of product contact equipment was not performed aseptically. For instance, during set-up of (b)(4) line, two personnel exposed the (b)(4) hopper to the ISO 7 environment. Additionally, an operator placed their foot into the ISO 5 enclosure when transferring the sterile hopper to the aseptic processing line. Your aseptic filling equipment design, suitability for intended use, cleanroom layout, HEPA-filtration coverage, protection of ISO 5 areas, and the number and complexity of personnel interventions during filling operations are deficient. Basic design deficiencies and manually intensive interventions in your operations compromise your ability to maintain aseptic conditions. Your firm also failed to ensure adequate environmental monitoring of classified areas used for aseptic production of sterile (b)(4) drug products. For example, The frequency of environmental monitoring was inadequate. You did not perform air monitoring of ISO 5 critical filling areas on (b)(4). In addition, ISO 5 surface monitoring was only performed (b)(4). Your processing lines were in production (b)(4). The frequency of personnel monitoring was inadequate. Personnel monitoring was not conducted for batches or was insufficient. These personnel were observed to perform critical ISO 5 interventions on the aseptic processing line. Furthermore, when personnel monitoring was

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Animal & Veterinary	**W**	MARCS-CMS 670835	During the inspection FDA collected a sample (FDA sample #1214888) of your in-process Woody's Pet Food Deli Raw Free Range Turkey with Supplements pet food for dogs and cats, lot code 08/31/24, from your facility. FDA laboratory analysis revealed this product was contaminated with Salmonella Reading and Listeria monocytogenes. Based on the analytical results, FDA considers the sampled product lot to be adulterated in that it bears or contains a poisonous or deleterious substance which may render it injurious to health.1 On September 19, 2023, you voluntarily disposed of Woody's Pet Food Deli Raw Free Range Turkey with Supplements pet food for dogs and cats, lot code 08/31/24. You failed to take measures, which are adequate to prevent adulteration of your animal food during the manufacturing, processing, packing, and holding of animal food, to significantly minimize or prevent the growth of undesirable microorganisms in your animal food, as required by 21 CFR 507.25(c)(2). Undesirable microorganisms include microorganisms that are pathogens, that subject animal food to decomposition, that indicate the animal food is contaminated with filth, or that otherwise may cause animal food to be adulterated (21 CFR 507.3). Specifically, your firm uses (b)(4), an acetic acid, PAA, and hydrogen peroxide (b)(4), as your method to eliminate pathogens from your raw pet food products. On August 31, 2023, FDA collected an in-process sample (FDA sample #1214888) of Woody's Pet Food Deli Raw Free Range Turkey with Supplements, lot code 08/31/24, which subsequently tested positive for Salmonella Reading and Listeria monocytogenes. This sample was taken after the application of (b)(4) and immediately prior to finished product packaging. Therefore, your use of (b)(4) is not adequate to prevent adulteration of your animal food. FDA previously found undesirable microorganisms in your finished raw pet food products, indicating a recurring issue at your firm. A sample of your Woody's Pet Food Deli Raw Cornish Hen Homemade Cat and Dog Food with Supplements, collected by FDA on November 30, 2021, tested positive for Salmonella enteritidis (FDA sample #1150234). In addition, your Woody's Pet Food Deli Raw Chicken Homemade Cat and Dog Food collected by FDA on August 20, 2019, tested positive for Salmonella Infantis and Salmonella Kentucky (FDA sample #1046805). You also responded that you are unable to eliminate pathogens completely. This is a concern because Salmonella is a pathogenic bacterium that can cause serious and sometimes fatal infections in both humans and animals. Infections can be especially serious in young children, elderly people, and others with weakened immune systems. The association between human illness or outbreaks of salmonellosis and Salmonella-contaminated pet foods is well established.8 In 2019, Salmonella Reading was found in three lots of your Woody's Pet Food Deli Raw Free Range Turkey and was implicated in part of a human illness outbreak investigated by the CDC.9,10 Association between Salmonella-contaminated pet food and pet illness has also been shown.11 Thus, FDA considers a pet food to be adulterated if it is contaminated with Salmonella. You have been previously informed on other occasions of the FDA's position regarding Salmonella in pet food, including in an Untitled Letter issued to your firm on September 2, 2022, and in teleconferences between FDA and your firm on August 30, 2019, and December 16, 2021. Your response is inadequate in that it did not propose changes to your process or add additional interventions to address the recurrence of Salmonella in your pet food. Use of Peroxyacetic Acid (PAA) During our inspection you provided the labeling and technical data sheet for (b)(4), which your firm uses as an antimicrobial treatment/kill step during processing of your raw meat pet food products. PAA is one of the substances that is in (b)(4). Our investigators noted you use a (b)(4) at a concentration of (b)(4) ppm for (b)(4) for all organ meat and a (b)(4) at a concentration of (b)(4) ppm for (b)(4) on all meat during production. 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

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Giles Scientific, Inc.			https://www.biomic.com/trinity-v3.html
Special Process Services, LC			https://www.linkedin.com/in/joseph-connaghan-b663929