Date of This Update: January 26, 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=203632	May contain generic E. coli.
Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=203836	Product may be contaminated with Listeria monocytogenes.
Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=203817	Possible Listeria monocytogenes contamination.
Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=203629	Lobster meat may be contaminated with Listeria monocytogenes.
Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=204139	Potential contamination with Salmonella Thompson,
Devices	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=203663	Sterilization failures when devices are sterilized per the Reprocessing Manual due to lack of drying time for the endoscope channel.
Devices	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=203602	Non-sterile product labeled as sterile was distributed.
Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=203626	Histamine, high total plate count, coliforms, and E.coli (serotype is unknown).
Biologics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=204293	Red Blood Cell products, lacking assurance of sterility, were distributed.

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Devices	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=203805	A complaint investigation showed that the bulk pellets (lot 794-142) were contaminated with Aspergillus flavus.
Devices	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=203724	Channel air drying process was not validated, and that a small percentage of scopes returned to customers after repair had a wet channel. Water remaining in the channel of the endoscopes has the potential for contamination that could lead to the risk of infection.
Drugs	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=204141	Non-Sterility: FDA found insanitary conditions and positive bacterial test results from environmental sampling at the manufacturing facility.
Veterinary	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=203833	potential salmonella
Biologics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=204391	Blood products, lacking assurance of sterility, were distributed.
Veterinary	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=203986	The firm was notified by the FDA that the product test positive for Salmonella.
Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=204326	Potential contamination with Burkolderia cepacia complex (B. cepacia)
Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=204309	Potential E. coli (EHEC) contamination.
Devices	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=204168	Routine quality control testing of affected blood culture identification panel with affected control panel may need to be amended, due to control panel/instrument characteristic changes, that lead C. tropicalis to be amplified in some portion of test runs, but then it's reported as "Not Detected" because the assay amplicon Tm is outside the acceptable limit assigned for calling positive results.

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Devices	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=204035	Product was re-processed and re-sterilized by a third party using packaging configurations and a sterilization process which are not approved by the manufacture and lack validation.
Devices	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=204279	A sterilization nonconformance prematurely aged the product, resulting in an inaccurate labeled expiration date.
Drugs	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=204066	Non-Sterility: FDA found insanitary conditions and positive bacterial test results from environmental sampling at the manufacturing facility.
Drugs	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=204512	Lack of assurance of sterility.
Devices	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=204176	Defect in the outer packaging of the Cranial Access Kits. can cause the packaging to split without any additional forces outside compromising the sterility of the device.
Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=204516	Potential contamination with Listeria monocytogenes.
Drugs	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=204241	Microbial Contamination of Non-Sterile Products: microbial contamination identified as Penicillium brevicompactum observed during routine ongoing stability testing.
Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=204628	Product contains yeast and mold.
Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=204865	Products may be contaminated with Listeria monocytogenes.

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Devices	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=204249	The product description on the labeling includes the word "Sterile" or STRL", however the contents of the solution inside the foil sachet is non-sterile.
Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=204575	The affected product is being recalled from the marketplace due to possible Salmonella contamination.
Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=204648	Cantaloupe containing products may be contaminated with Salmonella.
Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=204487	Salmonella
Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=204320	The affected product is being recalled from the marketplace due to possible Salmonella contamination.
Devices	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=204296	Ceiling mounted L-arm contains a rotation cover that may potentially be susceptible to falling if a collision between the L-arm and other hospital equipment (i.e., an operating light) were to occur result in injury or potential sterility issues due to the cover becoming loose.
Devices	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=204348	There is the potential that cooler-heater devices may contain bacterial contamination which could result in patient infection.
Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=204538	Potential Salmonella Contamination.
Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=204484	Salmonella contamination.

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Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=204460	TruFresh in Nogales, AZ issued a voluntary recall of its Malichita, Mexico-sourced whole cantaloupe sold in the United States for potential Salmonella contamination.
Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=204494	salmonella
Devices	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=204367	Sodium chloride irrigation USP, and sterile water for irrigation USP, that may be packaged inside kits, have the potential for a lack of sterility assurance, which could result in a nonsterile product, use of which could cause infection.
Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=204416	Potential contamination with Listeria monocytogenes.
Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=204796	Product may be contaminated with E-Coli and Pluralibacter Gergoviae.
Devices	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=204714	A sterilization nonconformance prematurely aged the product by 48.3 days, resulting in the expiration date on the label not being accurate. This nonconforming product was inadvertently distributed to customers. Increased risk to patients and healthcare providers using the product after the shortened expiration date of November 17, 2025.
Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=204613	Potential mold contamination.
Devices	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=204421	The sterility of microcatheter and infusion system devices cannot be guaranteed.
Devices	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=204795	Seal defects could compromise the ability of the product packaging to maintain sterility.

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Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=204690	Potential Salmonella Contamination.
Devices	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=204702	Firm is recalling all kits containing recalled lots of Nurse Assist Sterile 0.9% Normal Saline. Nurse Assist identified product in distribution for which the required sterility assurance level (SAL) of 10^-6 cannot be guaranteed. Risks to patients if product is used include blood stream infections, urinary tract infections, or respiratory infections; in the worst-case scenario, there is risk of sepsis or death.
Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=204786	Potential C. botulinum growth and toxin formation. Frozen bangus (milkfish) in reduced oxygen packaging does not contain instructions to keep frozen and instructions for proper thawing (e.g., "Important, keep frozen until used, thaw under refrigeration immediately before use.").
Drugs	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=205126	Lack of Sterility Assurance.
Drugs	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=205254	CGMP Deviations: Firm reported possible microbial contamination in the purified water used in the manufacturing of the products. No contamination was found in the final products.
Devices	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=204708	Sterility assurance cannot be guaranteed for external drainage systems due to incomplete bioburden testing.
Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=205118	The firm initiated a recall of SoyBean Sprouts because product tested positive for Listeria monocytogenes.
Devices	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=204552	Hole(s) to the outer pouch of the Introducer Kits (both trayed and non-trayed) may compromise the sterile barrier of the Introducer Kits. Non-sterile product exposes patients to the possibility of the introduction of micro-organisms into the vasculature and/or access site, leading to an infectious process, bacteremia or sepsis.
Drugs	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=205107	MICROBIAL CONTAMINATION OF NON-STERILE PRODUCTS - Presence of Acetobacter nitrogenifigens bacteria.

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Devices	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=204967	The strippers and cleavers are provided non-sterile and labelled as reusable/autoclavable. Olympus does not have validated cleaning and sterilization instructions. Use of a non-sterile fiber stripper or cleaver on a sterile fiber poses a risk of contamination.
Devices	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=204704	Express chest drains are pre-packaged with sterile water syringes which have bene recalled. If the device is not kept in an upright position, the patient may be exposed to infectious material. Subsequent hazards include but are not limited to infection, abscess, sepsis, and death.
Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=205075	Potential Salmonella contamination of Quaker Oats Chewy Granola Bars packed in gift baskets.
Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=204898	potential microbial contamination
Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=204994	The firm was notified by the Florida Department of Agriculture that the products test positive for Listeria monoctyogenes.
Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=204464	The select fresh-cut products were made from whole cantaloupe subject to a previously announced voluntary recall initiated by Sofia Produce, LLC dba Trufresh. The whole cantaloupe may have the potential to be contaminated with Salmonella.
Food/Cosmetics	**R**	https://www.accessdata.fda.gov/scripts/ires/?Product=205047	Potential contamination with Listeria monocytogenes
Foods	**C**	3011286443	You did not conduct operations under conditions and controls necessary to minimize the potential for growth or survival of microorganisms and contamination of food.
Drugs	**C**	3002779991	Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing.
Foods	**C**	3012673106	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**	3008764387	You did not conduct operations under conditions and controls necessary to minimize the potential for growth or survival of microorganisms.
Drugs	**C**	3005193435	Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written and followed.

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Foods	**C**	3000203945	You did not implement a written environmental monitoring plan designed to identify L. monocytogenes if it is present in the growing, harvesting, packing or holding environment. and You did not test spent irrigation water from each production batch of sprouts for E. coli O157:H7, Salmonella and pathogens reasonably necessary to minimize risk of serious adverse health consequences.
Foods	**C**	2130526	You did not test the quality of water using a scientifically valid method. and Your environmental monitoring plan does not include an adequate written corrective action plan.
Foods	**C**	3005596895	You did not conduct operations under conditions and controls necessary to minimize the potential for growth or survival of microorganisms.
Drugs	**W**	MARCS-CMS 657325	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)). 2. 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)). 3. Your firm failed to establish a system for monitoring environmental conditions in aseptic processing areas and an adequate system for cleaning and disinfecting the room to produce aseptic conditions (21 CFR 211.42(c)(10)(iv) and 211.42(c)(10)(v)). 4. Your firm failed to establish the accuracy, sensitivity, specificity, and reproducibility of its test methods, and you also failed to conduct appropriate laboratory testing to determine whether each batch of drug product purporting to be sterile conforms to such requirements (21 CFR 211.165(e) and 211.167(a)). 5. Your firm's quality control unit failed to exercise its responsibility to ensure drug products manufactured are in compliance with CGMP, and meet established specifications for identity, strength, quality, and purity (21 CFR 211.22).
Medical Devices	**W**	MARCS-CMS 660075	1. Failure to adequately ensure that when the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedure, as required by 21 CFR 820.75(a). For example, your firm did not maintain documentation of validation for the following processes: a. Ethylene Oxide (EO) sterilization of the probe cover kit containing the sterile gel pouch Your firm's EO sterilization validation was conducted for a kit containing another device, C-Arm Drape, that is also packaged in a Tyvek pouch. a. Your firm provided a new procedure, (b)(4) Procedure for Irradiation Sterilization Dose, to document the irradiation validation dose similar to the validation report in Exhibit 22. However, this document does not address the concern of your firm not being able to provide adequate records of the gel lots used during the sterilization validation. Additionally, there is no evidence of procedure effectiveness and documentation of training on the new procedure. 2. Failure to identify by suitable means the acceptance status of the product, to indicate the conformance or nonconformance of product with acceptance criteria, as required by 21 CFR 820.86. For example, your firm had several pallets of in-process product held next to finished products in an area designated for finished sterile product ready for release. Additionally, the sterility status of product was not identified (e.g., stickers affixed directly to finished product). Only a single loose paper with the lot number and one sterile color identifier ((b)(4)) was taped to the pallet.

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Drugs	**W**	MARCS-CMS 669488	In response to this letter, provide the following for all drug products imported to the United States prior to and after our 704(a)(4) request: A list of chemical and microbial test methods and specifications used to analyze each batch of your drug product before making a batch disposition decision, and the associated written procedures. 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.. The stability test results you provided were limited to pH, density, appearance, smell, color and strength. You failed to provide data for testing of impurities, and microbiological attributes (total counts and free of objectionable microorganisms).
Drugs	**W**	MARCS-CMS 669407	In response to this letter, provide the following for all drug products imported to the United States prior to and after our 704(a)(4) request: The chemical and microbiological quality control specifications you use to test and release each incoming lot of component for use in manufacturing. In response to this letter, provide the following for all drug products imported to the United States prior to and after our 704(a)(4) request: A list of chemical and microbial specifications, including test methods, used to analyze each batch of your drug products before a batch disposition decision. In addition, your stability data does not include testing for identity and strength. Therefore, the data does not demonstrate that the drug's active ingredient is stable throughout its shelf life. Also, the information provided does not include microbiological stability data. Without appropriate stability studies, you do not have scientific evidence to support whether your drug products meet established specifications and retain their quality attributes through their labeled expiry.

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Food & Beverages	**W**	MARCS-CMS 660360	1.You did not identify and evaluate a known or reasonably foreseeable hazard to determine whether it required a preventive control for your nRTE noodles products (i.e., wonton wrappers, egg roll wrappers, and noodles), as required by 21 CFR117.130(a)(1). Specifically, a. You did not identify and evaluate the hazard of bacterial growth and/or toxin formation due to lack of time/temperature control as a known or reasonably foreseeable hazard to determine whether it requires a preventive control for your noodle products during production. The noodles are (b)(4). Therefore, bacterial growth and/or toxin formation due to lack of time/temperature control is a known or reasonably foreseeable hazard to be considered for these products. Staphylococcus aureus (S. aureus), a bacterial pathogen that can contaminate food via worker's hands and skin, can grow and produce toxin if the noodle dough is subject to time/temperature abuse during production. The toxin is heat-stable and not easily destroyed by normal cooking temperatures. You do not know the water activity of the dough throughout drying, including whether and, if so, for how long it is above 0.85, which would support S.aureus growth and (potentially) toxin formation when the products are held at temperatures that support growth (e.g., 90°F) for sufficient time. In addition, you did not identify and evaluate the hazard of bacterial growth and/or toxin formation due to lack of time/temperature control as a known or reasonably foreseeable hazard to determine whether it requires a preventive control for your canton noodles during finished product storage. The canton noodles are treated as shelf stable, stored at ambient temperatures, and are not labeled to be kept refrigerated or frozen. You do not know the water activity of the finished product canton noodles, including whether it is above 0.85. When responding to this letter, you should provide a revised hazard analysis showing that you identified and evaluated bacterial growth and/or toxin formation due to lack of time/temperature control. If you determine that S. aureus requires a preventive control, you should include a Food Safety Plan including a preventive control (e.g., a process preventive control for time/temperature control during dough production and canton noodle finished product storage) to address the hazard. The implementation of these corrective actions will be evaluated during our next inspection. b. Mycotoxins – You did not identify and evaluate the hazard of mycotoxins as a known or reasonably foreseeable hazard to determine whether they require a preventive control for your noodle products. The noodles contain wheat flour, which has been associated with mycotoxins such as deoxynivalenol (DON). Therefore, contamination with mycotoxins is a known or reasonably foreseeable hazard to be considered for these products. A knowledgeable person manufacturing/ processing food in your circumstances would identify mycotoxins as a hazard requiring a preventive control(i.e., supply-chain control) in the wheat flour ingredient. Supply-chain controls include a supply-chain program as required by subpart G of 21 CFR part 117. We note that you receive a Certificate of Analysis (COA) from your supplier of the wheat flour ingredient. However, the COA does not address mycotoxins. You stated that you do not have a supply-chain preventive control to address the hazard of mycotoxins in wheat flour. On May 24, 2023, your Office Manager contacted your wheat flour supplier during the inspection and obtained a COA, which included an analysis for mycotoxins. However, you did not provide your revised hazard analysis showing that mycotoxins require a preventive control; you also did not provide a preventive control ensuring that mycotoxins would be controlled. In your response to this letter, you should include a Food Safety Plan including a supply-chain program covering mycotoxins in wheat flour used to make noodles. The implementation of these corrective actions will be evaluated during our next inspection. a. On May 2, 2023, during the production of canton noodles, lot number 05032023, in the Drying Room, where approximately (b)(4) of noodles are held each week, our investigators observed:

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Drugs	**W**	MARCS-CMS 660904	2. 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)). Media Fill Contamination Incidents You failed to appropriately evaluate a pattern of media fill failures in your facility and afford sufficient attention to potential correlations among these contamination events. Between February 2021 and March 2022, there were multiple aborted and contaminated media fills on (b)(4) filling lines (b)(4) and (b)(4) (solution and suspension lines). For example, In September 2021, you isolated a gram-negative microbe, Ralstonia picketii, from multiple media fill (b)(4) of Batch # (b)(4) manufactured on the (b)(4) suspension line. You identified multiple deviations such as damaged filter housing, choked (b)(4), dislocation of the filter, and ineffective (b)(4) processes. In November 2021, you isolated Pseudomonas stutzeri from one (b)(4) of media fill Batch # (b)(4) manufactured on the (b)(4) suspension line. This media fill (Batch # (b)(4)) was performed as part of the initial qualification of the suspension line and as a corrective action for a previously failed media fill on the same line (Batch #(b)(4)). You identified Pseudomonas stutzeri to be a gram-negative opportunistic pathogen. Your investigation, reviewed during the inspection and further described in your response, indicated this contamination was due to a puncture in the body of the (b)(4) by a (b)(4) during handling or movement of the filled samples, storage, or visual inspection, prior to incubation. However, you lacked adequate evidence that described mishandling of (b)(4). Further, your investigation also does not include comprehensive steps to prevent future mishandling of incubated units, and indicates use of (b)(4) will still be permitted. Your QU approved the investigation and the media fill run for Batch # (b)(4), and you used this media fill as one of three successful runs required to qualify filling line (b)(4) for suspension products. In March 2022, you isolated Stenotrophomonas maltophilia in multiple media fill (b)(4) of Batch # (b)(4). You identified Stenotrophomonas maltophilia to be a drug-resistant gram-negative emerging global opportunistic pathogen with a known propensity for biofilm formation. You determined the root cause to be a leakage caused by a damaged valve gasket and deformed filter. You failed to appropriately investigate root causes and implement effective CAPAs to prevent recurrence of contamination events. For example, you failed to substantively evaluate the personnel and environmental monitoring (EM) data obtained during the production of these media fill batches, and to comprehensively assess additional historical data from the manufacturing area. Your response is inadequate because there is no overall assessment of these atypical invalidations of media fills, explanation of the adverse pattern of gram-negative microbe findings in your aseptic processing operational environment, or major improvements to ensure more reliable aseptic operational design and equipment maintenance. The presence of any highly pathogenic microorganism in your aseptic processing environment presents a heightened risk to patients who are, for example, immunocompromised, have cystic fibrosis, or have chronic obstructive airway disease. Presence of such microbes should receive urgent investigation and effective remediation. Further, it is critical to ensure appropriate equipment design and maintenance, as equipment failures may not be easily observable and contamination events during commercial manufacturing may go undetected for substantial periods of time. It is essential to address potential contamination hazards in your manufacturing environment in a timely manner. Any adverse microbiological trends and potential routes of contamination should be identified promptly, allowing for implementation of appropriate follow-up measures to prevent contamination. It should also be noted that finished product testing alone cannot establish sterility of all units because contamination is typically episodic and not uniformly distributed. Environmental Monitoring

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Drugs	**W**	MARCS-CMS 665456	Adulteration Violations FDA laboratory testing of a batch of Dr. Berne's MSM DROPS 5% Solution drug product (lot 6786, “Best By 032025”) found that it contained microbial contamination. The sample results failed to meet USP <71>, sterility tests. Therefore, this drug product is adulterated under section 501(a)(1) of the FD&C Act, in that it consists in whole or in part of any filthy, putrid, or decomposed substances. Fungal and bacterial microorganisms were identified from drug product samples analyzed for sterility, which included, but were not limited to Exophiala sp. and Bacillus 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. During the FDA teleconference on August 21, 2023, you stated that your drug products are manufactured by a contract manufacturer, and you agreed to conduct a voluntary recall of the lot currently in U.S. distribution. On August 26, 2023, you voluntarily recalled lot 6786 of Dr. Berne’s MSM DROPS 5% Solution to the consumer level due to microbial contamination. In addition, you are voluntarily recalling all lots of Dr. Berne’s MSM DROPS 5% Solution, Dr. Berne’s MSM DROPS 15% Solution, Dr. Berne’s Organic Castor Oil Eye Drops, and Dr. Berne’s MSM MIST 15% Solution to the consumer level due to potential microbial contamination, as noted on the following FDA website: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/dr-bernes-whole-health-products-issues-voluntary-nationwide-recall-dr-bernes-msm-drops-5-and-15 On August 22, 2023, FDA issued the following drug alert warning to consumers not to purchase and to immediately stop using Dr. Berne’s MSM Drops 5% Solution due to bacterial contamination, fungal contamination, or both: https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-consumers-not-purchase-or-use-certain-methylsulfonylmethane-msm-eye-drops-due

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Drugs	**W**	MARCS-CMS 662868	B. During aseptic filling, non-viable particle (NVP) count limits were exceeded in ISO 5 aseptic processing areas and no investigations were conducted because these excursions did not persist for more than (b)(4), as stated in your procedure. You lacked an adequate system for handling NVP counts exceeding your action levels of NMT (b)(4) particles ≥ 0.5 µm/ft3 during aseptic processing operations. Line (b)(4) frequently failed to meet these ISO 5 limits. You routinely failed to investigate these high particulate levels in the ISO 5 aseptic processing operation. For example, while manufacturing (b)(4) injection, a (b)(4) product produced for the U.S. market, the NVP probe at the filling station, the probe at the infeed (b)(4), and the probe at the stoppering station failed the NVP count limit multiple times. In one instance, the filling machine automatically stopped as a result of these NVP alarms. There was no procedural requirement to clear any open product containers present at the time of the excursion. Your firm determined that no investigation would be done because the ISO 5 alarms did not individually persist for (b)(4). Excessive particulates in the ISO 5 environment can lead to non-viable or biological contamination of sterile drug products. 4. 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)). A. Your procedures did not include a requirement for smoke studies to be performed in dynamic conditions in classified critical areas. There have been no smoke studies to determine whether the "(b)(4) LAF [laminar air flow]" can provide appropriate unidirectional air during dynamic activities, such as loading of the (b)(4) into the (b)(4) restricted access barrier systems ((b)(4)RABS). The mobile LAF was not evaluated during the smoke studies under dynamic conditions. For example, the operator removes the (b)(4) tub from the mobile LAF and carries them under the "(b)(4) LAF" (which is classified as an ISO 7 area) and then into the (b)(4)RABS. Thorough smoke studies are essential to evaluate and qualify your aseptic processing operations and ensure appropriate implementation of needed design remediations. In your response, you indicate your procedures were revised to include instructions for conducting smoke studies under dynamic conditions. You state you have now performed smoke studies under dynamic conditions for the (b)(4) tub loading process including the mobile LAF and "(b)(4) LAF." You commit to an assessment for all filling lines of parenteral drug products to evaluate execution of smoke studies in static and dynamic conditions. Your response is inadequate. You do not provide the smoke study video and report evaluating unidirectional airflow patterns under dynamic conditions for the (b)(4) tub loading process, including mobile LAF and "(b)(4) LAF." B. The qualification of the (b)(4) cycle of the (b)(4) equipped with transport ports failed to ensure adequate decontamination and worst-case locations in the (b)(4) used in manufacturing. Specifically, the (b)(4) transport port (b)(4) used to transport components to the (b)(4) was not assessed with biological indicators at the (b)(4) of the (b)(4). In addition, the investigator observed an overlap and fold in the (b)(4) of the (b)(4) near the area where the (b)(4) attaches to the (b)(4) for which the qualification failed to address if this area can be reproducibly decontaminated by (b)(4). In your response, you acknowledge the observation that chemical and biological indicators were not placed at the (b)(4) of the (b)(4) transfer port and (b)(4) for (b)(4). We note a requalification was performed on the (b)(4) cited during the inspection and a report was provided. You commit to evaluating all (b)(4) and (b)(4) for appropriate sample locations. You commit to reviewing the

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Animal & Veterinary Drugs	**W**	MARCS-CMS 667614	FDA is particularly concerned about your unapproved animal drugs because they raise public health concerns. Available as over-the-counter drugs, they contain antimicrobials that are considered medically important in the treatment of human disease.1 Concern about the development of resistance to antimicrobials important in human medicine has led FDA to promote more judicious use of animal drugs containing medically important antimicrobials, including working toward ensuring that these drugs can be used in animals only under the supervision of a licensed veterinarian.
Animal & Veterinary Drugs	**W**	MARCS-CMS 667431	FDA is particularly concerned about your unapproved animal drugs because they raise public health concerns. Available as over-the-counter drugs, they contain antimicrobials that are considered medically important in the treatment of human disease.1 Concern about the development of resistance to antimicrobials important in human medicine has led FDA to promote more judicious use of animal drugs containing medically important antimicrobials, including working toward ensuring that these drugs can be used in animals only under the supervision of a licensed veterinarian.
Drugs	**W**	MARCS-CMS 666900	In response to this letter, provide: A comprehensive, independent review of your material system to determine whether all suppliers of components, containers, and closures, are each qualified and the materials are assigned appropriate expiration or retest dates. The review should also determine whether incoming material controls are adequate to prevent use of unsuitable components, containers, and closures. The chemical and microbiological quality control specifications established to release each incoming lot of components for use in manufacturing. In response to this letter, provide: A list of chemical and microbial specifications, including test methods, used to analyze each lot of your drug products before a lot 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.
Medical Devices	**W**	MARCS-CMS 667432	However, the instructions for use (IFU) for your firm's own brand and private label brand devices listed above also describe the process and acceptance criteria for "extended cycles." The IFU(s) also include a diagram showing pass/fail results and describe how to interpret the chemical indicator (CI) post-sterilization. This diagram shows in the noted table what the CI should look like after a passed or failed cycle when using the cycle specifications that were previously cleared under K191021; however, the table also includes a column for "extended cycles," which describes the use of extended cycles and the interpretation of extended cycle results. Your device was not cleared for extended cycle use. The extended cycle description in the labeling falls outside of the parameters in the cleared IFU as it suggests that the end user can extend the cycle on their own and follow the "accept/reject" diagram to interpret the results. The distribution of these devices for an extended cycle use without authorization results in improper use of the device which could result in improperly sterilized devices leading to patient infections and serious health risks. CIs are cleared with specific validated cycle parameters that should be clearly specified in the labeling. The addition of "extended cycle" sterilization cycles in the labeling represents a significant change or modification in the intended use of the device; therefore, a new 510(k) is required.

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Drugs	**W**	MARCS-CMS 659151	2. Your firm failed to clean, maintain, and 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, and you failed to establish and follow adequate written procedures for cleaning and maintenance of equipment (21 CFR 211.67(a) and (b)). Your cleaning procedures were not supported by validation studies, and you did not maintain appropriate cleaning records. Your manufacturing utensils and containers were unclean with what appeared to be residue from previous use. These conditions were originally cited during the 2015 inspection, uncorrected during the 2021 inspection, and continue to persist. Chemical and microbiological residues on equipment from previous manufacturing activities can adversely impact the purity, quality, and safety of drug products also manufactured on that equipment. Furthermore, these conditions extend to your raw material storage area, cleaning sink, and production area. These areas were observed to be in an unclean state and with disorderly placement of materials, which is inadequate to prevent contamination. In response to this letter, provide a corrective action and preventative action (CAPA) plan, based on the retrospective assessment of your cleaning program, that includes appropriate remediations to your cleaning processes and practices, and timelines for completion. Provide a detailed summary of vulnerabilities in your process for lifecycle management of equipment cleaning. Describe improvements to your cleaning program, including enhancements to cleaning effectiveness; improved ongoing verification of proper cleaning execution for all products and equipment; and all other needed remediations. 5. Your firm failed to establish and follow an adequate written testing program designed to assess the stability characteristics of drug products and to use results of stability testing to determine appropriate storage conditions and expiration dates (21 CFR 211.166(a)). Your firm does not have adequate stability data to show that the chemical and microbiological properties of your topical acne drug products for OTC human use remain acceptable throughout the labeled expiry period of 3 years, for example: Chemical test data for your Oxygenetix Institute Oxygenating Foundation Acne Control drug product exceeded the monograph acceptance criteria of (b)(4) increase at expiry for the active ingredient salicylic acid. While your firm could not provide an investigation for the OOS during the inspection, you state in your response that the increase was due to evaporation, and that measures have been taken to address the issue. However, you did not provide a detailed investigation identifying the root cause for the evaporation, nor supporting data to assure your CAPA is adequate. You failed to ensure microbiological test methods used by your contract testing laboratory (CTL) in your stability program were validated (or verified). Specifically, test methods referenced by your CTL are microbiological test methods intended for analyses of foods and cosmetics. Drug products must be tested using appropriate microbiological quality standards including total count and objectionable microorganisms. This may include, but not be limited to, applicable USP general chapters. It is essential to ensure that each of your finished drug products conform to appropriate microbiological specifications before release and throughout the drug product's life cycle. We discussed these issues with you during the 2021 regulatory meeting. Furthermore, your stability test data lacks appropriate evaluation of your drug products' antimicrobial effectiveness throughout its life cycle. Without appropriate stability data, you cannot ensure your drug products meet established specifications and all pre-determined quality criteria throughout the assigned shelf-life of your drug products. In response to this letter, provide:

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Food & Beverages	**W**	MARCS-CMS 659181	During our inspection eighty (80) environmental swabs were collected from various locations throughout your processing areas. FDA laboratory analysis of environmental sample 1204755 collected on February 27, 2023, confirmed eleven (11) swabs positive for Listeria innocua and two (2) swabs positive for Listeria innocua/welshimeri, both non-pathogenic Listeria species. The positive findings include the drain in the basin of the packaging room where our investigator observed standing brown liquid, on the floor next to exterior door in the production room, and middle of the floor of the basin located in the packaging room. We note that the investigator observed floors that were pitted and visibly unclean throughout the facility and floors are potential sources of Listeria, especially where there are cracks and crevices. Furthermore, during our previous inspection in April 2022, FDA laboratory analysis of environmental sample 1171554 consisting of fifty (50) swabs collected on April 11, 2022, confirmed two (2) swabs positive for Listeria innocua, one (1) swab positive for Listeria ivanovii, and one (1) swab positive for Listeria grayi. The presence of Listeria species such as Listeria innocua, welchimeri, ivanovii, grayi suggests that conditions also are suitable for survival and/or growth of Listeria monocytogenes, an environmental pathogen. As a manufacturer of RTE bakery products, you are responsible to ensure that you have appropriate procedures and practices to prevent Listeria monocytogenes contamination in your facility.
Drugs	**W**	MARCS-CMS 666442	2. Your firm failed to conduct microbiological testing before use of each lot of a component with potential for objectionable microbiological contamination in light of its intended use. (21 CFR 211.84(d)(6)). Your firm produces (b)(4) water that is used as a component in the production of many of your OTC drug products. Your firm failed to adequately monitor the microbiological quality of the water you use to manufacture your aqueous-based OTC drug products. Specifically, you only test your (b)(4) water for microbiological attributes and total organic carbon (TOC) on a (b)(4) basis. Water for pharmaceutical must be suitable for its intended use and routinely tested to ensure ongoing conformance with appropriate chemical and microbiological attributes. In response to this letter, provide: A commitment to perform retrospective testing of aqueous-based finished drug product retains, within expiry, to ensure they meet all microbiological quality attributes. A summary of your program for qualifying and overseeing contract facilities that test the (b)(4) water you produce. A commitment to perform increased microbiological testing of your (b)(4) water system until a qualification of the system is complete and an appropriate monitoring procedure is established. A commitment to develop a procedure governing your program for ongoing control, maintenance, and monitoring that ensures the system consistently produces water that meets (b)(4) Water, USP monograph specifications and appropriate microbial limits. In addition, your acceptance criteria for total plate count when performing microbiological testing of your (b)(4) water system is stringently “[n]o detectable levels ((b)(4) cfu/mL)”. Testing performed by your third-party laboratory indicates that you are meeting that specification for all (b)(4) of your points-of-use in your water system, even though you identified dead legs in points-of-use (b)(4) and (b)(4) in January 2023. Provide: o Your quality agreement with the third-party laboratory that performs microbiological testing of your (b)(4) water. o Your procedure for collecting, storing, and transporting (b)(4) water samples to your third-party laboratory, including chain-of-custody requirements. Identify if any additives/processes are introduced to the (b)(4) water samples prior to transporting to your third-party laboratory.

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Food & Beverages	**W**	MARCS-CMS 667551	The United States Food and Drug Administration (FDA) conducted an inspection of your ready-to-eat (RTE) raw milk cheese manufacturing facility located at 107 Oxbow Road., Milford, NY 13807-1131 from June 21 through July 28, 2023. 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). Additionally, 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. At the conclusion of the inspection, the FDA investigators issued your facility a Form FDA 483 (FDA-483), Inspectional Observations. L. monocytogenes is a pathogenic bacterium that is widespread in the environment and may be introduced into a food processing facility from raw materials, humans, or equipment. Without proper controls, it can proliferate in food processing facilities where it may contaminate food. Therefore, it is essential to identify the areas of the food processing plant where this organism is able to grow and survive and to apply controls or take corrective actions as necessary to eradicate the organism. Consuming foods contaminated with L. monocytogenes can lead to a severe, sometimes life-threatening illness called listeriosis, which is a major public health concern due to the severity of the disease, its high case-fatality rate, its long incubation time, and its tendency to affect individuals with underlying conditions. FDA laboratory analysis of environmental sample #1221906 collected at your facility on June 21, 2023 confirmed that four (4) of fifty (50) environmental swabs were positive for L. monocytogenes, and FDA laboratory analysis of environmental sample #1228986 collected at your facility on June 26, 2023 confirmed that four (4) of fifty six (56) environmental swabs were positive for L. monocytogenes. Of the positive findings, one (1) of the L. monocytogenes positive swabs was collected from the food contact surface of a cutting board that was being used to cut RTE Jersey Girl cheese. Furthermore, dating back to 2017, your firm has had history of finished product samples that have tested positive for L. monocytogenes. In 2017, New York State Department of Agriculture and Markets (NYSDAM) collected a finished product sample of your firm's Toma Celena cheese (lot #51017) which tested positive for L. monocytogenes. In response to this finding, your firm tested (b)(4) lots of finished products and found two additional lots (lots #52417 and #60717) to be positive for L. monocytogenes. Whole genome sequencing (WGS) was conducted on the above referenced L. monocytogenes isolates. Based on the results of the WGS analysis, the environmental swabs collected at your facility during FDA's most recent inspection and finished product samples from 2017 represent four (4) different strains of L. monocytogenes. None of them matched any clinical isolates. We advised you of the importance of these WGS results via a conference call on July 14, 2023, and again on July 20, 2023. The presence of L. monocytogenes in your facility and your products 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. Our findings indicate that your firm is neither achieving satisfactory control against the presence of L. monocytogenes within your facility nor implementing effective methods and controls to eliminate this human pathogen or minimize exposure to food and food-contact surfaces. Once it is established in a production area, personnel or equipment can facilitate the pathogen's movement and contamination of food-contact surfaces and finished product. It is essential to identify the harborage sites in the food processing plant and equipment where this organism is able to grow and survive and to take such corrective actions as are necessary to eradicate the organism.

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Food & Beverages	**W**	MARCS-CMS 659735	b. For your RTE seasoning products, 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 seasoning products which are exposed to the environment during blending and filling. 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, note that 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)). You do not have appropriate controls in place for contamination with environmental pathogens. You stated that you use Mrs. Meyer's Clean Day Multi-Surface Concentrate as the main cleaning solution for cleaning all areas of the facility including food-contact surfaces. This is labeled as a household cleaner, not for use on food-contact equipment in a food manufacturing facility. You further stated that you do not use any sanitizers at your facility, such as for food-contact surfaces. c. You did not identify and evaluate bacterial pathogens, such as Salmonella, as a known or reasonably foreseeable hazard to determine whether they require a preventive control. Your facility manufactures RTE seasoning products made from onion powder, garlic powder, white pepper, paprika, cayenne pepper and celery powder which have been associated with vegetative bacterial pathogens such as Salmonella. A knowledgeable person manufacturing/processing food in your circumstances would identify bacterial pathogens as a hazard requiring a preventive control. Further, a facility that identifies raw materials and other ingredients that require a supply-chain-applied control, such as Salmonella, 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 supplier verification activities (see 21 CFR § 117.410). You do not have an appropriate supply-chain program in place. For example, you do not approve suppliers or conduct appropriate supplier verification activities for the manufacturing of John Paine's Steak Beast Unleashed All Purpose Rub (Lot: JPUL230216004), which consists of salt, brown sugar, onion powder, garlic powder, white pepper, black pepper, paprika, cayenne pepper, celery powder, and hickory smoke seasoning. Salmonella in RTE seasoning products is a hazard that can cause serious adverse health consequences or death and thus 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. You did not identify and evaluate mycotoxins as a known or reasonably foreseeable hazard to determine whether they require a preventive control. Your facility manufactures and repackages RTE seasoning products made from white pepper, cayenne pepper, and paprika. These ingredients have been associated with mycotoxins. A knowledgeable person manufacturing/ processing food in your circumstances would identify mycotoxins as a hazard requiring a preventive control in these ingredients. Further, a facility that identifies raw materials and other ingredients that require a supply-chain-applied control, such as mycotoxins, 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 supplier verification activities (see 21 CFR § 117.410). You do not have this program in place.

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Biologics	**W**	MARCS-CMS 649343	1. Failure to establish appropriate written procedures designed to prevent microbiological contamination of drug products purporting to be sterile, including procedures for validation of all aseptic and sterilization processes [21 CFR 211.113(b)]. For example: a. Your firm has failed to validate the aseptic processes used to manufacture XoGlo®, XoGlo®Pro, and Amnio2X®. These products purport to be sterile and are expected to be sterile. b. You have not established appropriate written procedures for environmental monitoring in the aseptic processing areas where your products are manufactured. Specifically: i. Your written procedure for microbiological monitoring of surfaces, air, and personnel in the aseptic processing area indicates your action and alert limits for microorganisms are (b)(4) and (b)(4) CFUs, respectively.3 Your allowance for such high numbers of microorganisms could contribute to product contamination and pose a potentially significant safety concern. ii. You have not performed non-viable particulate monitoring of the aseptic processing areas in association with each production batch. This is insufficient to detect problems and demonstrate control of the aseptic processing areas during manufacturing. Additionally, you have not established alert or action limits for particulate monitoring. 2. Written records are not always made of investigations into unexplained discrepancies or the failure of a batch or any of its components to meet specifications whether or not the batch has already been distributed [21 CFR 211.192]. Specifically, you failed to document investigations for all unexplained discrepancies or the failure of batch to meet specifications. For example, you failed to document an investigation into the positive sterility result obtained for XoGlo®Pro lot 4000078P. All (b)(4) vials of this lot were distributed. 3. Each batch of drug product purporting to be sterile and/or pyrogen-free is not laboratory tested to determine conformance to such requirements [21 CFR 211.167(a)]. For example: a. Sterility samples of Amnio2x® are frozen prior to sterility testing. Freezing product has the potential to destroy any microbial content in the samples before testing; therefore, contamination, if present, may not be detected. b. Your written procedure for Amnio2x® specifies testing of (b)(4) vials for sterility regardless of lot size, which may consist of as many as (b)(4) vials. This does not ensure that sterility samples are representative of the lot size. 4. Failure to establish laboratory controls that include scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity [21 CFR 211.160(b)]. Specifically, you have not established scientifically sound and appropriate specifications to assure that your products conform to appropriate standards of identity, strength, quality, and purity. Your specifications are listed as “tentative.” 7. Failure to establish an adequate system for cleaning and disinfecting the room and equipment to produce aseptic conditions [21 CFR 211.42(c)(10)(v)]. For example, at the time of the inspection: a. You failed to validate your written cleaning procedure for your laminar flow (b)(4) and your cleanrooms where your products are manufactured. Additionally, you failed to establish the effectiveness of disinfectants used in this procedure. b. Your written procedure for cleaning the (b)(4) and cleanroom did not specify the contact time for disinfectants. c. Your firm documented major and minor cleaning of (b)(4) and cleanrooms used in manufacturing of your products; however, your written procedures did not define the minor and major cleaning methods.

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Reason for Recall/Warning Letter may be redacted to remove information identifying specific companies.
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Drugs	**W**	MARCS-CMS 667057	For example, your QU failed to ensure the following: Appropriate laboratory determination of satisfactory conformance to final specifications for your finished drug products (21 CFR 211.165(a). Adequate design and procedures for production and process controls for drug products and for maintenance and monitoring of your water system used to manufacture drug products, including a lack of investigation into out of limit microbiology test results during the installation of your water system (21 CFR 211.100(a) and 211.192)). 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.
Biologics	**W**	MARCS-CMS 662942	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.

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Animal & Veterinary Food & Beverages	**W**	MARCS-CMS 663413	In your firm's response, you state your system is designed to remove packing and other foreign materials and render sterile any contaminants from pests so that they do not pose a threat to animal health "as demonstrated by our never having made an animal sick in the history of our company." You have not provided supporting evidence that your system is capable of sterilizing the product. Furthermore, your response does not sufficiently address other animal food safety hazards that could result from the observed storage conditions, such as: nutrient degradation, contamination with toxins from mold formation, or contamination from chemical hazards and physical hazards (e.g., gravel). In addition, you did not identify and evaluate the known or reasonably foreseeable hazard of recontamination with environmental pathogens in the processing steps following the dryer, which you have identified as your control for pathogens in your ingredients. Your hazard analysis for (b)(4) documents a CCP (critical control point) at the dryer step to control pathogens, which you determined are a hazard requiring a preventive control. Your hazard analysis states that you operate the dryer at an "average temperature of (b)(4)" for a minimum of (b)(4).5 However, you failed to validate the use of your dryer as a preventive control to significantly minimize or eliminate pathogens in your (b)(4). For example, you were unable to provide any scientific or technical evidence or studies that determined whether the dryer operating at (b)(4) at a minimum of (b)(4) would be adequate to control pathogens, as required by 21 CFR 507.47(b)(2). In your written response you discussed the preliminary results of your study to confirm the time it takes for material to pass through the dryer, your plans to continue the study, and intent to update your HACCP Plan after you gathered additional data. You also provided laboratory analysis reports from a 3rd party laboratory for samples your firm collected after the drying step for an unspecified lot(s) of your (b)(4). These samples were received by the laboratory on June 29, 2023. We acknowledge the analytical results do not report detectable levels of bacteria including Escherichia coli (generic), Salmonella spp., and Listeria spp., and are below detectable limits for mycotoxins. However, your study appears to be based on a single set of analytical data. This is not a sufficient representation of the tonnage for the products you manufacture, and it is unclear what the starting pathogen load was prior to the lot being processed through your dryer step. You have not submitted scientific and technical evidence, or a validation study that demonstrates your process control at the dryer step will effectively control the pathogen hazard. We are therefore unable to determine the adequacy of your response.
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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