DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse Rm900 200 Chestnut St Philadelphia, PA 19106 (215)597-4390 Ext:4200 Fax:(215)597-0875	12/21/2022-2/17/2023* FEI NUMBER 3015728839

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Marcellino E. Valdez, Plant Manager

FIRM NAME	STREET ADDRESS
BlendHouse LLC	61 Vanguard Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Reading, PA 19606-3765	Infant Formula Base Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:
OBSERVATION 1
You did not establish a system of process controls covering all stages of processing that was designed to ensure that infant formula does not become adulterated due to the presence of microorganisms in the formula or in the processing environment.

Specifically,

You were notified, on 10/17/2022, by your parent company, ByHeart, that product used in finished product Lo(b) (4) , consisting of (b) (4) cases, in which your base product was a component of, tested positive for Cronobacter sakazakii (b) (4) (b) (4) This finished product is a non-exempt milk based infant formula for which you are the supplier of infant formula base. Your infant formula base product manufactured during a (b) (4) (b) (4) (producing Lots (b) (4)) was ultimately associated with the finished product positive incident.

1. In response to this Cronobacter sakazakii positive you conducted a root cause investigation which was documented in your "Event Reporting and Investigation Form" under "Event Number 22138." Your root cause investigation concluded that the 3rd party contracted laboratory post-production sample handling and compositing was the most probable cause for the positive Cronobacter sakazakii. Your corresponding corrective actions involved "additional preventative measures" at the 3rd party laboratory and "until the corrective actions are adequately addressed, ByHeart will be utilizing alternative laboratories for microbiological testing."

   On 11/07/2022, the 3rd party contract laboratory provided a "OOS Result Investigational Report for Microbiological Testing" regarding the Cronobacter sakazakii findings in finished product Lo(b) (4) , which concluded that "Laboratory error was not found or supported."

2. Additionally, review of your "Event Reporting and Investigation Form" under "Event Number 22107" found that on 08/24/2022, your infant formula base, Lot (b) (4) was analyzed by the 3rd party laboratory which tested positive for Cronobacter sakazakii . Your root cause analysis concluded that "PROD-310-SOP Interventions into Product Contact Zones was not followed during the work completed on back pressure (b) (4) . The exposure of a product contact surface to the environment such as a processing line (b) (4)) is highly risky, particularly when intervention procedures are not followed, and effective cleaning is not completed afterwards. This scenario poses the potential introduction of Cronobacter to the

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product (b) (4) ." As noted in your investigation, the "entire lot of (b) (4) was rejected and shall be disposed of (b) (4)

Further, our record review of Event Number 2299 found that on 07/21/2022, your infant formula base, Lot (b) (4) (b) (4) was analyzed by your 3rd party laboratory. The analysis documented Aerobic Plate Count was out of specification with (b) (4) (b) (4) . Your root cause analysis concluded that "PROD-310-SOP Interventions into Product Contact Zones" was not followed during work (b) (4) is (b) (4) . You lacked documentation that sanitation practices were followed during the Event. Lot (b) (4) was later used to manufacture ByHeart finished product Lot (b) (4) .

3. Further, between 7/20/2022 and 09/21/2022, our review of your environmental monitoring program, "Environmental Monitoring Positive Response Action Plan QUAL-510.06-WI" and associated implementation records confirmed the presence of Cronobacter spp. in your manufacturing environment. Examples of environmental monitoring findings that were not adequately addressed regarding root cause analysis include:

a. On 07/25/2022, you were notified by your 3rd party laboratory of Cronobacter spp. on the floor after removal of a skylight in the ceiling in a low hygienic area. Confirmation of Cronobacter sakazakii was received on 07/26/2022. Event # 2290 was created and determined the area was "briefly exposed to the outside environment for approximately 1 minute… The exposure to the outside highly likely introduced cronobacter." You do not document, reference, or link this in the root cause analysis evaluation of this Event within your "Environmental Monitoring Program (EMP) Review" of Event 22138. The evaluation of this finding in Event 22138 reads, "… swabs were in specification < (b) (4) CFU/swab except for (b) (4) room…" Further, this Cronobacter spp. is linked to a water event (see Item 4 of this Observation).

b. On 08/01/2022, you were notified by your 3rd party laboratory of Cronobacter spp. on the (b) (4) base (medium care area) leading to the (b) (4) room. Confirmation of Cronobacter sakazakii was received on 08/05/2022. Also, during this time vector swabs were missed on one day 08/20/2022 and were restarted on 08/21/2022-08/30/2022. Event # 2298 was created, and it was determined the cleaning frequency of (b) (4) was inadequate and was changed to (b) (4) cleaning and also the (b) (4) was determined to not be an effective sanitizer on the door and was changed to (b) (4) . Your Event 2298 record states this area is, "… not in foot traffic…". However, we observed that you move pallets of infant formula base at this door. Employees access this area via pallet jacks and/or forklifts. Furthermore, you did not evaluate employee foot traffic within your root cause analysis regarding Event 22138.

c. On 08/27/2022, you were notified by your 3rd party laboratory of Cronobacter spp. on the (b) (4) room. Confirmation of Cronobacter sakazakii was received on 09/04/2022. On 08/30/2022, you were notified by your 3rd party laboratory of Cronobacter spp. on the (b) (4) cart. Confirmation of Cronobacter sakazakii was received

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on 09/02/2022. Event #22106 was created, and it determined the cleaning frequency of this room is not effective. The frequency of cleaning wa(b) (4) and was updated to "at least (b) (4) Further noted was "operations conducts(b) (4) (b) (4) cleaning in the area after production; however, the cleaning instruction and documentation for records are also insufficient." Your root cause analysis of Event 22106 did not evaluate possible sources, such as the positive Cronobacter spp. finding in infant formula base on 08/24/2022 (see Item 2 of this Observation). Further, your Event 22138 documents evaluation of your EMP occurred 07/13/2022-08/27/2022. You did not include this finding in your Event 22138 record. Therefore, you did not adequately evaluate root cause analysis of during your EMP review.

d. On 08/30/2022, you collected environmental swabs. Third-party laboratory results received on 09/06/2022 documented (b) (4) presumptive positive for Cronobacter spp. You received these results on 09/06/2022 and you requested confirmation testing of the(b) presumptive positives via email. The laboratory responded indicating(b) of the samples were confirmed negative but provided no COA's or formal analyses data. They also indicated the remaining(b) presumptive positive samples would receive confirmation testing. At this point you considered the initial (b) (4) as closed due to the lab stating they were confirmed negative. You proceeded to treat the remaining(b) unconfirmed sites as positives and began (b) (4) of vector swabbing. An email dated 12/27/2022 from your 3rd party laboratory documented confirmation testing had never been conducted on any of the(b)(presumptive positives. This indicates the (b) (4) presumptive positives referenced above were not subject to confirmation testing by the laboratory nor appropriate investigation and vectoring were done by your firm. The locations of these (b) (4) samples were in (b) (4), (b) (4) areas of your firm. You did not create an Event for this finding in accordance with your "Event Reporting and Investigation Procedure QUAL-509.05-WI." Therefore, no root cause investigation was performed and no corrective action was taken. Furthermore, you did not evaluate these findings in your Event 22138 record.

e. On 09/21/2022, you were notified by your 3rd party laboratory of Cronobacter spp. on the floor of the(b) (4) room in a low hygienic area. We observed this area is used for employees to gown before entering the manufacturing environment. We observed employees' garments, such as pants, touch the floor while gowning. This sample was later confirmed to be undetected for Cronobacter spp. but one of the vector swabs collected was confirmed to Cronobacter (b) (4) on 10/07/2022. Event #22116 was created and determined the floors were only being sanitized with(b) (4) (b) (4) and "the use of(b) (4) as a cleaner prior to sanitizing with(b) (4) was not a requirement." Proper cleaning and sanitizing of surfaces include the removal of organic matter so that sanitization can occur to reduce pathogenic microbial growth. You did not include this sample in your EMP Review of Event 22138. Therefore, you did not evaluate the lack of cleaning agent used in a high foot traffic area regarding Event 22138.

4. Lastly, review of your "Event Reporting and Investigation Form" found that you identified two water events in where water from outside of your facility's building leaked into your manufacturing areas.

Specifically, on 12/15/2022, you identified a leak through a deteriorated sealant around a louver installed on level(b) of the dryer

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(b) (4) of (b) (4) dryer (b) (4). Event #22179 was created and determined a worn sealant around the frame of the (b) (4) and heavy wind and rain all day on 12/15/2022 caused the leak. During swabbing conducted on 12/15/2022, four swabs were detected positive for Cronobacter spp. in four locations of the dryer (b) (4) They were 1). Level (b) (4) dryer (b) (4) next to repainted surface, 2). Level (b) (4) dryer (b) (4) next to repainted surface (a different swab point), 3). Level (b) (dryer (b) (4) (b) (4)) table, and (b) (4) Level (b) (dryer (b) (4) (b) (4)) table. At the time of the water event on 12/15/2022, bulk infant formula base powder lot # (b) (4) was being produced.

Specifically, on 06/23/2022, you identified a leak through a skylight installed on the roof of the milk processing room. Event #2270 was created and determined heavy rain on 06/23/2022 caused the leak. Cronobacter spp. was discovered by your environmental monitoring program after (see Item 3a of this Observation). At the time of the water event on 06/23/2022, bulk infant formula base powder lot # (b) (4) was being produced.

OBSERVATION 2

You did not ensure that equipment or a utensil used in the manufacture, processing, packing, or holding of an infant formula were of appropriate design to facilitate their intended function.

Specifically,

On 09/02/2022 you manufactured Lot (b) (4). At 11:54 four plastic pieces were found on the (b) (4) after Tank (b) (4) and (b) (4) during cleaning after the production run. This equipment is located in the (b) (4) room.

You created Event # 22108 to determine the source/cause of the plastic pieces. Your investigation revealed that the most probable cause was that the (b) (4) Operator dropped a plastic sample cup in Tank (b) (4) on 09/01/2022 between 15:06 and 15:40 while the Operator was conducting a (b) (4) sample test. It was further determined via comparison of plastic sample cups used that an 8 oz plastic sample cup was the type dropped into Tank (b) (4)

You recovered 17.5 grams of plastic. Your Event record states 8 oz plastic cup weighs 29.7 grams on average.

You were not able to account for all plastic pieces.

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***DATES OF INSPECTION**
12/21/2022(Wed), 12/22/2022(Thu), 12/27/2022(Tue), 12/28/2022(Wed), 1/03/2023(Tue), 1/04/2023(Wed), 1/05/2023(Thu), 1/06/2023(Fri), 1/10/2023(Tue), 1/11/2023(Wed), 1/17/2023(Tue), 2/01/2023(Wed), 2/02/2023(Thu), 2/03/2023(Fri), 2/08/2023(Wed), 2/09/2023(Thu), 2/10/2023(Fri), 2/17/2023(Fri)

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."