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	12/11/2023-1/19/2024* FEI NUMBER 3015728839

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jonathan A. Fenstermacher, Plant Manager

FIRM NAME	STREET ADDRESS
BlendHouse LLC	61 Vanguard Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Reading, PA 19606-3765	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 ensure that all surfaces that contacted ingredients, in-process materials and infant formula were cleaned and sanitized and maintained to protect infant formula from being contaminated by any source.

Specifically, on 9/7/2023, during a routine post-CIP inspection, your batching operators found an unidentifiable "red stain" on the inside of the batch tank T2200, which prompted the operators to inspect the (b) (4) tank. During this inspection of the (b) (4) tank, your employees found mold above the water line. The (b) (4) system circuits the batch room tanks, and the dryer feed lines. The (b) (4) tank holds clean water for (b) (4) system during cleaning. Upon the discovery of the mold in the (b) (4) tank, on 9/7/2023, prior to cleaning and sanitizing, you collected swabs for yeast and mold confirmation testing. These swabs were collected from the interior of the (b) (4) tank where you found growth. The lab report for these swabs collected said "many confluent colonies" of mold growth were seen in the (b) (4) plates (the report EMP23010, referred to these findings as "TNTC" -too numerous to count).

In your "Environmental Positive Investigation Form report" number EMP23010, under "INVESTIGATION SUMMARY AND RCA", it stated "Mold present in the air was likely introduced to the interior surface of the tank". Review of your "Event Reporting and Investigation Form/ Environmental Positive Investigation Form" from January of 2022 through December of 2023 for mold events indicated that there were two prior mold findings (Event Number 2240 and EMP Report Number EMP23002) in the same hygienic area (Batch Room).

Event number 2240 (Event dated 4/13/2022) documented an out of specification results of yeast and mold in ambient air in the batching room as likely the result of "build-up" (off white and black in color) found underneath the exterior surface of the homogenizer and the (b) (4) (b) (4) tank. EMP Report Number EMP 23002 (Event dated 3/13/2023) documented finding of mold on the water pipe on north/west corner of rear batching room. Yet you stated that prior to mold finding in 9/7/2023, your firm did not clean the interior of the (b) (4) tank, because the tank is used only for holding clean water. Furthermore, your batching employee stated he inspects the water level and the interior of the (b) (4) tank prior to each CIP cycle, but you do not maintain any record of such inspections. As such, cannot determine when mold was first introduced into the tank.

OBSERVATION 2

You did not maintain a building used in the manufacture, processing, packing or holding of infant formula in a clean and sanitary condition.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Melissa M Schafer, Investigator
Elizabeth P Mayer, National Expert
Alan D Centi, Investigator
Kyle D Covill, Investigator
Kawshalya Pathiraja, Investigator

X Melissa M Schafer Investigator Signed By: Melissa M. Schafer -S Date Signed: 01-19-2024 13:01:18

DATE ISSUED
1/19/2024

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	12/11/2023-1/19/2024* FEI NUMBER 3015728839

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Jonathan A. Fenstermacher, Plant Manager	
FIRM NAME BlendHouse LLC	STREET ADDRESS 61 Vanguard Dr
CITY, STATE, ZIP CODE, COUNTRY Reading, PA 19606-3765	TYPE ESTABLISHMENT INSPECTED Manufacturer

Specifically, on 12/11/2023, during the walk thru inspection of your facility, we observed an active water leak at the Dryer Level [(b)(4)] roof-below the gas burner. The duct work for this gas burner is located in the ceiling where the water was dripping.

Your facility has experienced many roof leaks during the year which has intruded into the manufacturing areas in different hygienic areas. The roof to the manufacturing facility is composed of five different sections, the age of which was unable to be determined by you or the roofing company. Events are created by your firm to document/investigate/determine the risk of an external water leak. Below is a summary of external roof leaks for the year 2023 categorized by hygiene area.

Packing Room [(b)(4)] – Critical Hygiene Area

On 09/24/2023, LN23019 was created for a water leak that occurred in packing room [(b)(4)] from the ceiling near the hatch door handle. There was a similar leak in this area according to your records previously on 05/04/2022. Lot 26723D1P2206-VA-BR was in production during this time.

On 10/14/2023, (20 days later) LN23021 was created for a water leak that occurred in packing room [(b)(4)] from the ceiling at the corner of the light near the sack conveyor. No product was being manufactured at the time.

Dryer Tower (b) (4) High (Care) Hygiene Area

On 03/28/2023, LN23004 was created for a water leak that occurred in Dryer Tower- Level [(b)(4)] and Level [(b)(4)] on a beam and wall opposite the side of the dryer. No product was being manufactured at the time.

On 04/01/2023, 04/15/2023, 04/30/2023 and 06/06/2023; LN23003, LN 23005, LN23007 and LN23008 respectively, were created for a water leak that occurred in Air Compressor ((b) (4)) and Fire Suppression ((b) (4)) rooms. No product was being manufactured at the time.

On 06/25/2023, LN23010 was created for a water leak that occurred Air Compressor ((b) (4)) and Electrical rooms ((b) (4) [(b)]). No product was being manufactured at the time.

On 07/09/2023, LN23012 was created for a water leak that occurred in (b) (4) room. Lot 19023D1P2206-VA-BR was in production during this time.

On 07/24/2023, 08/08/2023 and 09/07/2023; LN 23013, LN23015 and LN 23018 respectively were created for a water leak that occurred in (b) (4) room. No product was being manufactured at the time.

On 07/25/2023, LN23014 was created for a water leak that occurred in Dryer Tower- (b) (4) at Exit Door (due to door seal being damaged). Lot 26023D1P2206-VA-BR was in production during this time.

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	12/11/2023-1/19/2024* FEI NUMBER 3015728839

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jonathan A. Fenstermacher, Plant Manager

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

On 08/10/2023, LN23016 was created for a water leak that occurred in Dryer Tower-Level (b) (4) (exhaust fan) side down to Level (b) (4) Leak was discovered at the end of production for Lot 22123D1P2206-VA-BR.

On 08/13/2023, LN23017 was created for a water leak that occurred in Air Compressor and Fire Suppression rooms Lot 22523D1P2206-VA-BR was in production during this time.

On 12/11/2023, LN23026 was created for a water leak that occurred in Dryer Tower-Level (b) (4) duct. No product was being manufactured at the time.

OBSERVATION 3
You did not exclude pests from your food plant to protect against contamination of food.

Specifically, on 12/11/2023, during the walk thru inspection of your facility, we observed at the Dryer Level (b) (several flies actively flying around the ceiling and a dead fly on the ledge. The Dryer is a High Hygiene Area.

Furthermore, on our walk thru inspection of your facility, an investigator observed a fly land on the arm of your plant manager just outside the door leading to the anteroom for Packing room (b) (4) . Packing room (b) (4) is a Critical Hygiene area.

On 11/28/2023, (b) (4) (Pest Control Company) performed a comprehensive inspection of your manufacturing building located at 61 Vanguard Drive. The Drying tower was identified as "the hub of insect activity lately", entry points were noted (exterior and interior), and the area of the chemical storage cage. The 8 page report included pictures of areas with gaps on the Drying tower, chemical storage cage, tank farm, employee main door entrance, maintenance door entrance, batching room ceiling, etc.

Reviewing your pest control records from 01/01/2023 thru 12/31/23, revealed your firm had varied miscellaneous flying pests activity during the (b) (4) , and (b) (4) of 2023. Areas of concern noted are:

***Please note for the chart the following: ILT= Insect Light Trap, the number for each (b) (4) represents the total number of flying pests for all ILTs in that area.*

Area	ILT #s	(b) (4)	(b) (4)	(b) (4)
Dryer- All Levels (High Hygiene Area)	7,8,9,10,14	399	1,760	608
Minor Ingredient	1	1,090	675	60

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Melissa M Schafer, Investigator
Elizabeth P Mayer, National Expert
Alan D Centi, Investigator
Kyle D Covill, Investigator
Kawshalya Pathiraja, Investigator

X Melissa M Schafer Investigator Signed By: Melissa M. Schafer -S Date Signed: 01-19-2024 13:01:18

DATE ISSUED
1/19/2024

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	12/11/2023-1/19/2024* FEI NUMBER 3015728839

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jonathan A. Fenstermacher, Plant Manager

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

Staging Area (Low Hygiene Area)				
Maintenance (Limited Access)	2,12,15,16	4,175	9,720	835

OBSERVATION 4
You did not implement a system of production and in-process controls for an infant formula.

Specifically, the SOP PROD-310-SOP, "Interventions into Product Contact Surfaces" is maintained, which provides specific instructions on required procedures that must be strictly followed when interventions into product contact zones are necessary. The SOP states that for interventions after the (b) (4)) system, "a minimum of (b) (4). of (b) (4) must be discarded upon restarting". Interventions are documented on the form PROD-310.01-FM, "Verification of Product Contact Zone Intervention Procedures". Approximately, 24 interventions were performed from 6/24-9/29/23 and review of form PROD-310.01-FM indicated that on 7/11/23, 9/8/23 and 9/18/23, post-(b) (4) interventions were performed yet a minimum (b) (4) was not conducted as required by the firm's SOP.

For the interventions on 7/11/23 and 8/5/23, the (b) (4) dryer (b) (4) were removed or changed, and no (b) (4) was performed; for the intervention on 9/8/23, the autosampler in Packaging Room (b) (4) was repaired and only a (b) (4) was performed and finally, for the intervention on 9/18/23, the primary (b) (4) on the (b) (4) dryer was jammed, and no (b) (4) was conducted.
In addition, the SOP PROD-310-SOP, "Interventions into Product Contact Surfaces" states that "Notify QA of an intervention, as QA will observe and document the intervention activities". On 6/26/23, an intervention was performed but a quality assurance technician was not present as required by the SOP.

OBSERVATION 5
You did not monitor the temperature in a thermal processing equipment at a point where temperature control is necessary to prevent adulteration.

Specifically, the document, "DSI CCP Check Form", effective date 11/13/23 is utilized to manually document critical parameters every (b) (4) minutes for the (b) (4)) system, which is the final "kill step" for the product. The minimum processing temperature is (b) (4) and the maximum flow rate is (b) (4)); operating parameters are (b) (4) F or higher at (b) (4) . To ensure that the minimum temperature is achieved, there is a temperature indicating device (TID) and a temperature recording device (TRD) at the hold tube outlet. The DSI CCP Check Form states, "Notify your Supervisor immediately if the chart recorder is reading higher than the

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Melissa M Schafer, Investigator
Elizabeth P Mayer, National Expert
Alan D Centi, Investigator
Kyle D Covill, Investigator
Kawshalya Pathiraja, Investigator

X Melissa M Schafer
Investigator
Signed By: Melissa M. Schafer -S
Date Signed: 01-19-2024
13:01:18

DATE ISSUED
1/19/2024

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	12/11/2023-1/19/2024* FEI NUMBER 3015728839

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jonathan A. Fenstermacher, Plant Manager

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

indicating thermometer or if it has a greater than (b) (4) difference". During this inspection, batch records were reviewed for ByHeart milk-based powdered infant formula with iron. For Lot 179 (production date (b) (4)), review of DSI CCP Check Form identified 13 instances of the TRD reading higher than the TID and 24 instances that the two devices read more than (b) (4) apart. For Lot 192 (production date (b) (4)), review of DSI CCP Check Form identified 12 instances of the TRD reading higher than the TID and 30 instances that the two devices read more than (b) (4) apart. The operator did not notify their supervisor nor was this issue identified during record review by management. Both lots were released.

In addition, the temperature of the TRD is obtained from the HMI screen and not from the TRD unit itself, which does provide a digital readout. The TRD is located on the same control panel as the TID.

OBSERVATION 6

You did not minimize the potential for contamination of raw materials through the use of appropriate measures.

Specifically, in Building (b) (4), in the Minor Ingredient Dispensing Room referred to as "MIDU", minor ingredients including vitamin and mineral premixes are weighed into smaller containers; partial containers of major ingredients are also weighed. During the weighing process, ingredients are exposed to the environment. The MIDU room is a high hygiene area and is adjacent to the warehouse, which is a low hygiene area; the MIDU room doors open directly into the warehouse. In the MIDU room, the air pressure is not monitored to ensure that it is under positive pressure to prevent the introduction of potential air contaminants from the warehouse; the air pressure in the warehouse is also not monitored.

In addition, ambient air sampling is performed in production areas including the MIDU room; records were reviewed from January 2022-December 2023. In the MIDU room, mold was identified in air samples on two occasions, 8/6/22 and 1/20/23. The root cause investigations determined the most likely source as the room's air vents.

***DATES OF INSPECTION**

12/11/2023(Mon), 12/12/2023(Tue), 12/13/2023(Wed), 12/14/2023(Thu), 12/15/2023(Fri), 12/18/2023(Mon), 12/19/2023(Tue), 12/20/2023(Wed), 1/11/2024(Thu), 1/12/2024(Fri), 1/19/2024(Fri)

X Alan D Centi
Investigator
Signed By: 2001860402
Date Signed: 01-19-2024 13:01:57

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Melissa M Schafer, Investigator Elizabeth P Mayer, National Expert Alan D Centi, Investigator Kyle D Covill, Investigator Kawshalya Pathiraja, Investigator	X Melissa M Schafer Investigator Signed By: Melissa M. Schafer -S Date Signed: 01-19-2024 13:01:18	1/19/2024

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."