DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115	2/11/2025-2/20/2025* FEI NUMBER 1921383

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
John van der Hulle, Plant Director

FIRM NAME	STREET ADDRESS
Blendhouse Allerton,LLC	211 N Central Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Allerton, IA 50008	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 approved and released for use an ingredient that was not manufactured, packaged, labeled, or held under conditions to prevent adulteration.

Specifically, your firm approved and released the use of (b) (4) ingredient for use in manufacturing infant formula base bulk powder, that was not held under conditions to prevent adulteration. On 12/27/2024, a truck load of (b) (4) pallets of raw ingredients were received from your third party contracted warehouse; these included (b) (4) pallets of (b) (4) (b) (4) pallets of (b) (4) and (b) (4) pallets of (b) (4) (b) (4) (b) (4) Your firm received/approved/released for use (b) (4) pallets in the manufacturing of infant formula base bulk powder, after 1 pallet of the shipment (b) (4) (b) (4) contained evidence of rodent activity including torn bags and rodent excreta. After an initial evaluation, your firm destroyed and rejected this 1 pallet while using all others in the shipment prior to adequately investigating the root cause.

Then on 1/13/2025, a truck load of (b) (4) pallets raw ingredients were received from your third party contracted warehouse; these included (b) (4) pallets of (b) (4) lots (b) (4) and 1 pallet of (b) (4) Upon receipt, your warehouse employees broke down one pallet from the shipment for inspection for rodents/rodent activity. During this inspection, your employees did not find any rodents and/or rodent activity, as such you accepted the shipment and stored it in your warehouse until need for use on 1/21/2025, and on 1/23/2025. On both 1/21/2025 and 1/23/2025, your employees pulled one pallet of

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Kawshalya Pathiraja, Investigator Stephen G Mclane, Investigator Ron R Pearson, Investigator Joselin P Baray-Alvarado, Investigator Lloyd M Luapula, Investigator Marc Balzarini, Investigator X Kawshalya Pathiraja Investigator Signed By: Kawshalya Pathiraja - S Date Signed: 02-20-2025 15:20:51	2/20/2025

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115	2/11/2025-2/20/2025* FEI NUMBER 1921383

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
John van der Hulle, Plant Director	
FIRM NAME Blendhouse Allerton,LLC	STREET ADDRESS 211 N Central Ave
CITY, STATE, ZIP CODE, COUNTRY Allerton, IA 50008	TYPE ESTABLISHMENT INSPECTED Manufacturer

(b) (4) on each day for use. Upon bag-by-bag inspection during staging, on each of the days, your employees found rodent activity in each of the two pallets. Your firm received/approved/released for use (b) (4) pallets in the manufacturing of infant formula base bulk powder, after 2 pallets of the shipment (b) (4) contained evidence of rodent activity including loose powder and rodent excreta. Your firm rejected and destroyed these 2 pallets while using all others in the shipment prior to adequately investigating the root cause.

The above-mentioned raw materials received on 12/27/2024 (BOL (b) (4)), and on 1/13/2025 (BOL (b) (4)) are used in the manufacturing of the following infant formula base powder lots, (b) (4) (b) (4) (b) (4)

Additionally, on 2/20/2025, we observed your pre-weighing operations, and saw the exterior of the paper bags containing (b) (4) touched the employees' smock arms when lifting to pour the ingredients into another bag. The same employees' arm that was in contact with the exterior of the bags would go inside the milk bag for scooping. The employees did not change smocks, gloves, nor wash hands and/or sanitize hands in-between tasks.

OBSERVATION 2

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

Specifically, review of your pest management program from 1/16/2024-current, indicated a finding of a dead mouse on 1/22/2024 east of the QA Lab, seeing a live mouse in the (b) (4) on 12/3/2024, and catching mouse in a snap trap inside the (b) (4) Room on 12/15/2024. Moreover, there were rodent catches on the exterior premises, notably, in November 2024, and in December 2024 there were 11 and 8 catches in traps on the exterior premises, respectively. Also, currently, you are investigating rodent

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115	2/11/2025-2/20/2025* FEI NUMBER 1921383

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
John van der Hulle, Plant Director	
FIRM NAME Blendhouse Allerton,LLC	STREET ADDRESS 211 N Central Ave
CITY, STATE, ZIP CODE, COUNTRY Allerton, IA 50008	TYPE ESTABLISHMENT INSPECTED Manufacturer

activity found in raw material, (b) (4) During our walk through, we found a potential harborage sites at Warehouse (b) (4) Room (b) (4) end wall. However, you have not taken actions to eliminate all potential harborage areas.

OBSERVATION 3

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

Specifically, on 2/14/2024, we observed on the floor of dryer level (b) (4) near the exhaust fan, on multiple locations, rusty surfaces and the epoxy on the (b) (4) surfaces was peeling. Also, the floor under the (b) (4) air duct has rust on the floor. This creates a harder to clean surface thus leading to potential harborage areas for pathogenic microorganisms. Last time the leve (b) (4) floor near the exhaust fan was swabbed was on 10/10/24, one swab near (b) (4) was collected. Moreover, you had (b) (4) confirmed Cronobacter *Sakazakii* positive findings at level (b) (4) floor from 1/2/2024-2/6/2025. Also, you stated that the leve (b) (4) floor under the (b) (4) air duct has not been swabbed in the past year (1/2/2024-current). You had 4 confirmed Cronobacter *Sakazakii* positive findings at level (b) (4) floor from 1/2/2024-2/6/2025.

Moreover, you were unable to provide information as to when the floor conditions have changed (rust and/or peeling) in dryer level (b) (4) and in level (b) (4)

This is a repeat observation from the previous inspection(s) conducted on 06/30/2022 (written observation).

***DATES OF INSPECTION**

2/11/2025(Tue), 2/12/2025(Wed), 2/13/2025(Thu), 2/14/2025(Fri), 2/17/2025(Mon), 2/18/2025(Tue), 2/19/2025(Wed), 2/20/2025(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Kawshalya Pathiraja, Investigator Stephen G Mclane, Investigator Ron R Pearson, Investigator Joselin P Baray-Alvarado, Investigator Lloyd M Luapula, Investigator Marc Balzarini, Investigator	X Kawshalya Pathiraja Investigator Signed By: Kawshalya Pathiraja - S Date Signed: 02-20-2025 15:20:51	2/20/2025

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115	2/11/2025-2/20/2025* FEI NUMBER 1921383

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

John van der Hulle, Plant Director

FIRM NAME	STREET ADDRESS
Blendhouse Allerton,LLC	211 N Central Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Allerton, IA 50008	Manufacturer

X Stephen G Mclane
Investigator
Signed By: Stephen G. Mclane -S
Date Signed: 02-20-2025 15:21:27

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Kawshalya Pathiraja, Investigator
Stephen G Mclane, Investigator
Ron R Pearson, Investigator
Joselin P Baray-Alvarado, Investigator
Lloyd M Luapula, Investigator
Marc Balzarini, Investigator

X Kawshalya Pathiraja
Investigator
Signed By: Kawshalya Pathiraja -S
Date Signed: 02-20-2025 15:20:51

DATE ISSUED
2/20/2025

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."