

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

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| DISTRICT ADDRESS AND PHONE NUMBER 550 W. Jackson Blvd., Suite 1500 Chicago, IL 60661-4716 (312) 353-5863 Fax: (312) 596-4187 | DATE(S) OF INSPECTION 9/20/2021-9/24/2021 |
| | FEI NUMBER 1815692 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TJ Hathaway , Site Director

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|--|---|
| FIRM NAME Abbott Nutrition | STREET ADDRESS 901 N Centerville Rd |
| CITY, STATE, ZIP CODE, COUNTRY Sturgis, MI 49091-9302 | TYPE ESTABLISHMENT INSPECTED Infant Formula 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 maintain a building used in the manufacture, processing, packing or holding of infant formula in a clean and sanitary condition.

Specifically, on 09/20/2021 and 09/21/2021, in Building (b) (4) Dryer (b) (4), standing water was observed in the following locations: under and adjacent to the (b) (4) air handling unit, outside the (b) (4) door associated with the Dry Blending Room and in the clean-out-of-place (COP) area. On 09/23/2021, in the same room, standing water was observed on the floor below the (b) (4)

On 09/23/2021, a forklift was observed moving ingredient pallets from the liquid processing mineral storage location to the Building (b) (4) Dryer (b) (4) location. The forklift was numbered (b) (4) and displayed a sign reading "Liquid Processing Room Only". Additionally, wooden pallets with ingredients for the liquid processing operation were stored in the same area. Finally, a box fan with a sign reading "Liquid Line" was observed blowing in the direction of the (b) (4) cabinet in Building (b) (4) Dryer (b) (4). This fan was observed with extensive debris and dust-like build up.

OBSERVATION 2

You did not install a (b) (4) capable of (b) (4) when (b) (4) is used at a product filling machine.

Specifically, on Filler Lines (b) (4), the finished product is (b) (4). On Filler Line (b) (4) (b) (4) is used at the following locations: filler (b) (4), seamer (b) (4), and seamer. On Filler Line (b) (4) is used at the following locations: filler (b) (4) and seamer (b) (4).

AMENDMENT 1

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|---------------------------------|---|---|--------------------------|
| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE Daniel B Arrecis, Investigator Elizabeth P Mayer, National Expert | Daniel B Arrecis Investigator Signed By: Daniel B. Arrecis -0 Date Signed: 09-24-2021 10 38 17 X | DATE ISSUED 9/24/2021 |
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OBSERVATION 3

Personnel working directly with infant formula, its raw materials, packaging, or equipment or utensil contact surfaces did not wash hands thoroughly in a hand washing facility at a suitable temperature after the hands may have become soiled or contaminated.

Specifically, on 09/20/2021, in the Mineral Weigh Room, the Processing Operator did not sanitize nor change his gloves after touching non-food contact surfaces; immediately afterwards, he touched food contact surfaces including the inside of the potassium chloride ingredient bag and a clear plastic bag used to store weighed ingredient.

In addition, the Operator's exposed wrists, between the glove and smock cuff, were observed entering the inside of the potassium chloride ingredient bag when scooping ingredients.

OBSERVATION 4

An instrument you used to measure, regulate, or control a processing parameter was not properly maintained.

Specifically, your firm does not calibrate the following system components:

- The flow sensor for the (b) (4) system located on the product line between the (b) (4) pasteurizer and (b) (4) Dryer
- The pressure sensor for Tank (b) (4)
- The pressure sensors for Tanks (b) (4)
- The flow meters for the bulk oil silos into Tank (b) (4)

OBSERVATION 5

AMENDMENT 1

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You did not monitor the temperature in a thermal processing equipment at a frequency as is necessary to maintain temperature control.

Specifically, review of Master Work Order 01-0X290-MWO (Alimentum Dryer) for the product Alimentum Advance (packaging dates 04/21/2021, 04/25/2021, 06/18/2021, 07/14/2021 and 07/17/2021) did not document the indicating thermometer temperature for the (b) (4) pasteurizer. Temperature is identified as a critical control point (CCP).

X Elizabeth P Mayer
National Expert
Signed By: Elizabeth P. Mayer-S
Date Signed: 09-24-2021 10:38:49

AMENDMENT 1

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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."