DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION						
DISTRICT ADDRESS AND PHON		DATE(S) OF INS	021-9/24/2021			
Chicago, IL 6		FEI NUMBER	nort			
	Fax: (312) 596-4187	181569	2			
NAME AND TITLE OF INDIVIDUA	AL TO WHOM REPORT ISSUED	<u> </u>				
TJ Hathaway ,	, Site Director					
FIRM NAME	K-1	STREET ADDRESS	A3:			
Abbott Nutrit		901 N Centervil	le Rd			
Sturgis, MI 4		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.						
OBSERVATION You did not main formula in a clean	intain a building used in the manufa an and sanitary condition.					
Specifically, 09/20/2021 and 09/21/2021, in Building Dryer 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).						
location to the Bu Processing Room		ft was numbered with ingredients for the	and displayed a sign ne liquid processing ssing" was observe	reading "Liquid operation were d blowing in the		
OBSERVATION 2 You did not install a capable of (b) (4) when (b) (4) is used at a product filling machine.						
77.70	Filler Lines (b) (4) the finished pro- used at the following locations: filler is used at the followi	A STATE OF THE STA	A STATE OF THE PARTY OF THE PAR	b) (4) eamer. On Filler er/(b) (4)		
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Daniel B Arrecis, Investigat Elizabeth P Mayer, National		Daniel B Arrecis investigator Signed By Daniel B, Arrecis -0 Date digned 09-24-2021 X 09-36-39	DATE ISSUED 9/24/2021		

	TH AND HUMAN SERVICES G ADMINISTRATION
DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 1500	9/20/2021-9/24/2021
Chicago, IL 60661-4716	FEI NUMBER
(312)353-5863 Fax: (312)596-4187	1815692
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
TJ Hathaway , Site Director	
FIRM NAME	STREET ADDRESS
Abbott Nutrition	901 N Centerville Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Sturgis, MI 49091-9302	Infant Formula Manufacturer

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:

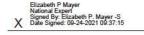
- The flow sensor for the (b) (4) system located on the product line between the (b) (4) pasteurizer and (b) (4) Dryer
- The pressure sensor for Tank
- The pressure sensors for Tanks (b) (4)
- The flow meters for the bulk oil silos into Tank

OBSERVATION 5

EMPLOYEE(S) SIGNATURE		DATE ISSUED
Daniel B Arrecis, Investigator Elizabeth P Mayer, National Expert	Daniel B Arrecis investigator Signed By Daniel B. Arrecis -8 Date Signed 09-24-2021 X 09-36-39	9/24/2021

FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS PAGE 2 of 3 PAGES

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION DISTRICT ADDRESS AND PHONE NUMBER 550 W. Jackson Blvd., Suite 1500 9/20/2021-9/24/2021 FEI NUMBER Chicago, IL 60661-4716 1815692 (312)353-5863 Fax: (312)596-4187 NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED TJ Hathaway , Site Director FIRM NAME STREET ADDRESS Abbott Nutrition 901 N Centerville Rd CITY, STATE, ZIP CODE, COUNTRY TYPE ESTABLISHMENT INSPECTED Sturgis, MI 49091-9302 Infant Formula Manufacturer 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).



SEE REVERSE

EMPLOYEE(S) SIGNATURE Daniel B Arrecis, Investigator OF THIS PAGE | Elizabeth P Mayer, National Expert

DATE ISSUED 9/24/2021 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."