DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313)393-8139	1/31/2022-3/18/2022* FEI NUMBER 1815692

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

FIRM NAME	STREET ADDRESS
Abbott Laboratories dba Abbott Nutrition	901 N Centerville Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Sturgis, MI 49091-9302	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 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,

A. FDA environmental samples collected on 2/1/22-2/2/22 during this inspection confirmed the presence of *Cronobacter sakazakii* on zone two and zone three surfaces in medium and high care areas of powdered infant formula production, as indicated by firm management and Policy Document ANPPR06-003 "Zone Definitions" (version 2.0, effective date 5/18/16) which defines low, medium, and high care areas.

Positive environmental sites for *Cronobacter sakazakii* were as follows:

1. In the packaging room for filler line (b)(4) the hinge attachment and bolt heads on the top, clear cover of the scoop hopper was swabbed and was positive for *Cronobacter sakazakii*. This scoop hopper is utilized to feed scoops, which are placed directly inside infant formula containers and contact product. This was collected from a zone two surface. You consider this a high care area. At the time

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X Alexandra A Carrico Investigator Signed By: Alexandra A Carrico -S Date Signed: 03-18-2022 1 : 9:32

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of swabbing, Similac Pro-Total Comfort with HMO infant formula powder (batch (b) (4)) was being packaged.

2. On the east side of the (b) (4) , the foot/base of a structural support piece of (b) (4) dryer # and the immediate surrounding floor was swabbed and was positive for *Cronobacter sakazakii*. This was collected from a zone three surface. You consider this a medium care area. At the time of swabbing, (b) (4) dryer # was in a clean-in-place (CIP) cycle.

3. In the (b) (4) Room on the (b) (4) of (b) (4) dryer # there was duct tape on the floor; debris was observed beneath and on top of the duct tape. The area between the duct tape and the wall was swabbed and was positive for *Cronobacter sakazakii*; this area was directly across from the door entry into the room. This was collected from a zone three surface. You consider this a medium care area. At the time of swabbing, (b) (4) dryer (b) (4) was in a CIP cycle.

4. In the (b) (4) Room located on the (b) (4) of (b) (4) dryer (b) (4) the floor and the (b) (4) (b) (4) door was swabbed and was positive for *Cronobacter sakazakii*. This was collected from a zone three surface. You consider this a medium care area. At the time of swabbing, (b) (4) dryer # was in a CIP cycle.

B. Between 9/25/19 and 2/20/22, your firm's environmental samples and finished product testing confirmed the presence of *Cronobacter* spp.

1. Environmental Samples: Your firm identified the presence of *Cronobacter* spp. in medium and high care areas of powdered infant formula production through sampling on eight occasions between

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10/10/19 and 2/2/22; two of those samples were taken during sister swabbing with the FDA. During the root cause analysis initiated in response to FDA environmental samples collected on 2/1/22-2/2/22 and your sister swabs collected on 2/1/22, your firm identified the presence of *Cronobacter* spp. in low, medium, and high care areas of powdered infant formula production on 20 occasions between 2/6/22-2/20/22.

2. Finished Product: Review of your firm's Non-Conformance Reports (NCRs) indicated that two finished products tested positive for *Cronobacter* spp. as follows:

   i. NCR (b) (4) (9/25/19) for Similac Alimentum infant formula powder (batch (b) (4) . This powdered infant formula was dried on (b) (4) dryer (b) (4) dry blended with xanthan gum, and filled on filler line # (b) (4)

   ii. NCR (b) (4) (6/22/20) for Similac for Spit-Up infant formula powder (batch (b) (4)). This powdered infant formula was dried on (b) (4) dryer (b) (4) dry blended with rice starch, and filled on filler line # (b) (4)

C. On 1/31/22, water was observed in the (b) (4) dryer # (b) (4) while the (b) (4) dryer was running Similac Total Comfort infant formula powder (batch (b) (4) :

1. On the (b) (4) , water was on the floor due to a (b) (4) leak from the inle (b) (4) . This water was dripping from the valves onto the (b) (4) floor. Per firm management, the leak was the result of a (b) (4) , which was compromised (Work Order #90361314). Water events associated with the inlet (b) (4) were also reported on 2/1/21 (Work Order

#89251658), 11/4/21 (Work Order #90094256 and Work Order #90094248) and 1/21/22 (Work Order #90329087).

2. On the (b) (4), water was around the floor drain near the potassium hydroxide (KOH) tanks.

3. On the (b) (4), water was at the floor/wall junction near the floor scrubber.

4. In the basement, water was on the floor by the (b) (4) which was adjacent to the (b) (4) (b) (4) system of (b) (4)

Standing water observed in powdered infant formula production areas is a repeat observation from the FDA inspection dated 9/20/21-9/24/21.

D. From 1/1/20-2/1/22, your firm identified 310 water events including water leaks, moisture and condensation in dry powdered infant formula production areas. These events do not include routine CIP cycles of equipment in these areas.

OBSERVATION 2

You did not ensure that all surfaces that contacted infant formula were maintained to protect infant formula from being contaminated by any source.

Specifically,

A. (b) (4) dryers (b) (4) are CIP'd at a minimum of (b) (4). From 12/31/19-2/4/22, (b) (4) dryer (b) (4)

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had (b) (4) CIP cycles and from 12/31/19-2/6/22. (b) (4) dryer (b) (4) had (b) (4) CIP cycles. During the CIP cycle, water is introduced into the (b) (4) dryer environment. At the end of the CIP cycle, a "dry-out" step is performed. For (b) (4) dryer # (b) (4) the dry-out step is (b) (4) and for (b) (4) dryer (b) (4), the dry-out step is (b) (4) In addition, management stated that the dry out steps for (b) (4) dryers were not validated to ensure complete drying is achieved.

B. Per your firm's (b) (4) dryer inspection reports, (b) (4) dryers (b) (4) have a history of internal deterioration dating back to September 2018. The most recent (b) (4) dryer inspections in August 2021 showed six instances of cracks and pits in the main chamber were recorded for (b) (4) dryer # (b) (4) and six instances of cracks, pits and damage in the main chamber and (b) (4) were recorded for (b) (4) dryer (b) (4) Ten cracked braces were also identified in the (b) (4) for (b) (4) dryer (b) (4)

Furthermore, both FDA and your firm found evidence of *Cronobacter* spp. in your powdered infant formula production environment. Your firm also identified *Cronobacter* spp. in finished powdered infant formula products.

OBSERVATION 3

Your investigation file on a complaint did not include the determination as to whether a hazard to health exists and the basis for that determination.

Specifically,

A. During the inspection we followed-up on the following FDA consumer complaints, which were all manufactured at your facility:

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1. FDA Consumer Complaint # 171222 detailing a *Cronobacter sakazakii* illness and death associated with 7 oz. Similac Pro-Total Comfort infant formula powder with batch # (b) (4) (Abbott Nutrition complaint ID: 554270)

2. FDA Consumer Complaint # 170177 detailing a *Cronobacter sakazakii* illness associated with 12.5 oz. Similac Sensitive infant formula powder with batch # (b) (4) (Abbott Nutrition complaint ID: 540628)

3. FDA Consumer Complaint # 171771 detailing a *Cronobacter sakazakii* illness associated with 12.4 oz. Similac Advance infant formula powder with batch # (b) (4) (Abbott Nutrition complaint ID: 564946)

4. FDA Consumer Complaint # 171087 detailing a *Salmonella newport* illness associated with 19.8 oz. Similac Alimentum infant formula powder with batch # (b) (4) (Abbott Nutrition complaint ID: 564943)

Your complaint investigations did not identify the root causes of the *Cronobacter sakazakii* and *Salmonella newport* illnesses reported from these complaints. Additionally, your complaint investigations treated infant death and infant illness the same.

B. Your Standard Operating Procedure (SOP) AN04-01-001 "Complaint Management and Investigations" (version 25, effective date 2/28/21 and version 26, effective date 12/21/21) states that retained samples are evaluated for microbial analysis in the following circumstances:

1. "When requested by Medical Safety and Surveillance for specific cases for Adverse Events (including Adverse Event trends) determined on a case by case basis (such as Cronobacter species, food poisoning, bacterial contamination, infection, etc.)"

2. "When it is determined during the course of the complaint investigation that there is a potential for the distributed product not to comply with specifications."

On 1/31/22, your firm provided the Complaint Detail Report with the status "Closed-Done" for FDA Consumer Complaint # 171222 (Abbott Nutrition complaint ID: 554270) detailing a *Cronobacter sakazakii* illness and death associated with 7 oz. Similac Pro Total Comfort infant formula powder with batch # (b) (4) During the investigation of this complaint, the Abbott Nutrition Medical Safety and Surveillance (ANMSS) team did not request that retain samples be tested for this lot in accordance with SOP AN04-01-001 "Complaint Management and Investigations". The final medical and quality assessments for this Complaint Detail Report were signed on 1/5/22.

OBSERVATION 4

Personnel working directly with infant formula, its raw materials, packaging, or equipment or utensil contact surfaces did not wear necessary protective apparel.

Specifically,

A. On 1/31/22, in (b) (4) dryer (b) (4) we observed an employee exit the elevator and enter the room with the (b) (4) , passing by a shoe spray station and failing to spray the soles of their shoes with

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sanitizer. At the same time this was observed, the nozzle of the sanitizer bottle was set to stream instead of spray while other individuals were spraying the soles of their shoes, which did not allow a uniform coating of sanitizer on the soles of shoes. This was observed while (b) (4) dryer # was running Similac Total Comfort infant formula powder (batch #(b) (4) .

B. On 2/24/22, your firm provided a draft root cause analysis dated 2/8/22 in response to the FDA environmental samples collected on 2/1/22-2/2/22 and your sister swabs collected on 2/1/22. You then provided an explanation of the root cause analysis, stating that from 1/24/22-2/9/22 approximately, (b) (4) contractors were present at the firm to perform work in Building primarily in the (b) (4) dryer (b) (4). The contractors walked on the roof with their captive footwear; upon returning into the building, they did not sanitize nor change their shoes.

These actions do not comply with your SOP ST-1000.08 "Dress Code and Personal Hygiene" (version 58, effective date 11/5/21), which states that "Contractors shall bag outdoor non-captive safety shoes and walk them to the designated shoe changing areas to change from captive safety shoes to non-captive safety shoes. Upon re-entering the plant, the process will reverse in order and outdoor non-captive shoes will be bagged and returned to their designated cubby or storage location."

Furthermore, the FDA found evidence of *Cronobacter sakazakii* in (b) (4) dryer (b) (4) from environmental samples collected on 2/1/22. Your firm found evidence of *Cronobacter* spp. in (b) (4) dryer (b) (4) from your sister swabs collected on 2/1/22 and your vector swabbing conducted during your root cause analysis.

C. On 1/31/22-2/4/22 and 2/8/22, we observed employees wearing their captive shoes walking in hallways,

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the cafeteria, and exiting the restroom. Between 1/31/22-2/12/22 employees, visitors, and contractors were not required to spray their captive shoes with sanitizer before entering the production area.

*DATES OF INSPECTION

1/31/2022(Mon), 2/01/2022(Tue), 2/02/2022(Wed), 2/03/2022(Thu), 2/04/2022(Fri), 2/08/2022(Tue), 2/16/2022(Wed), 2/17/2022(Thu), 2/18/2022(Fri), 2/21/2022(Mon), 2/22/2022(Tue), 2/23/2022(Wed), 2/24/2022(Thu), 2/25/2022(Fri), 2/28/2022(Mon), 3/02/2022(Wed), 3/03/2022(Thu), 3/09/2022(Wed), 3/10/2022(Thu), 3/14/2022(Mon), 3/15/2022(Tue), 3/16/2022(Wed), 3/17/2022(Thu), 3/18/2022(Fri)

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Investigator
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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."