DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 1500 Chicago, IL 60661-4716 (312)353-5863 Fax:(312)596-4187	9/16/2019-9/24/2019* FEI NUMBER 1815692

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Patrick A. Cooper, Site Director

FIRM NAME	STREET ADDRESS
Abbott Nutrition	901 N Centerville Rd
CITY, STATE, ZIP CODE, COUNTRY Sturgis, MI 49091-9302	TYPE ESTABLISHMENT INSPECTED 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 test a representative sample of a production aggregate of a powdered infant formula at the final product stage and before distribution to ensure that the production aggregate meets the required microbiological quality standards.

Specifically, on 09/16/2019, your firm was observed collecting 30 samples of Similac Pro Sensitive Batch No. (b) (4) during packaging on Packaging Line (b) (4). Your firm's document, Document ID: AN06-99-004, Global Microbiological Standards, Effective Date 26-Jun-2019, page 27 of 41, 5.5.6.1, notes sixty samples for Salmonella spp testing will be collected (b) (4) (b) (4).

---

*DATES OF INSPECTION

9/16/2019(Mon), 9/17/2019(Tue), 9/18/2019(Wed), 9/19/2019(Thu), 9/24/2019(Tue)

X Dariusz Galezowski
Investigator
Signed By: Dariusz Galezowski -S
Date Signed: 09-24-2019 14:28:11

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Daniel B Arrecis, Investigator Dariusz Galezowski, Investigator X Daniel B Arrecis Investigator Signed By: Daniel B. Arrecis -S Date Signed: 09-24-2019 14:27:31	9/24/2019

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."