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	8/23/2021-8/26/2021
	FEI NUMBER 1819504

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Scott A. Fisher, Site Director

FIRM NAME	STREET ADDRESS
Mead Johnson Nutrition	2400 W Lloyd Expy
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Evansville, IN 47712-5095	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

A temperature-indicating device was not installed where it could be accurately and easily read.

Specifically, on the cooker shell of your continuous agitating steam retort (13oz line), the temperature indicating devices ((b) (4) and (b) (4)), located at the shell inlet and outlet, are not easily readable due to being obstructed by the reel arms, and positioned in an area that is not well lit.

OBSERVATION 2

A record was not was not made of a critical factor specified in the scheduled process.

Specifically, review of the record, "Production Quality Audit Process Control 13 Ounce Line CCP", (b) (4) , indicated that readings of the temperature recording device (TRD) are only (b) (4) documented at the start of production. As such, you do not ensure that the process temperature charted on the TRD does not read higher than the temperature indicating device (TID). Process temperature is a critical factor according to your scheduled process.

In addition, review of the record, "Venting Procedure Checklist 13 Ounce Can Line CCP", dated (b) (4) indicated that the vent temperature is not (b) (4) documented at the start or the end of the venting process.

OBSERVATION 3

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Daniel B Arrecis, Investigator Elizabeth P Mayer, National Expert	X Daniel B Arrecis Investigator Signed By: Daniel B. Arrecis -S Date Signed: 08-26-2021 16:43:46	8/26/2021

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CITY, STATE, ZIP CODE, COUNTRY Evansville, IN 47712-5095	TYPE ESTABLISHMENT INSPECTED Infant Formula Manufacturer

Observation and measurement of an operating condition was not recorded at intervals of sufficient frequency to ensure that commercial sterility of the food product was being achieved.

Specifically, on the aseptic (b) (4) line, critical factors, which identify the maintenance of commercial sterility, are not (b) (4) documented for the processor, aseptic surge tank and filler between the sterilization of equipment and the start of production.

For example, review of the records, "Aseptic Filler Pre-sterilization Log CCP" and "32oz. Aseptic Filler Production Log CCP" dated (b) (4), respectively, indicated that critical factors were not documented between the end of sterilization at (b) (4) on (b) (4) and the start of filling at (b) (4) on (b) (4)

In addition, critical factor alarms for the processor, aseptic surge tank, and filler are not routinely challenged; they were previously challenged in 2017 when the system was commissioned.

X Elizabeth P Mayer
National Expert
Signed By: Elizabeth P. Mayer -S
Date Signed: 08-26-2021 16:44:32

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Daniel B Arrecis, Investigator Elizabeth P Mayer, National Expert X Daniel B Arrecis Investigator Signed By: Daniel B. Arrecis -S Date Signed: 08-26-2021 16:43:46	8/26/2021

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."