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	12/19/2023-2/2/2024* FEI NUMBER 1417217

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mike Klein, Site Director

FIRM NAME	STREET ADDRESS
The Quaker Oats Co.	1703 E Voorhees St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Danville, IL 61834-6256	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

Your written process monitoring procedures were not appropriate to significantly minimize or prevent the hazard requiring a preventive control.

Specifically, you use a (b)(4), located at (b)(4), as a kill step to control the hazard of pathogens in the manufacturing of oats and wheat into Chewy Bars. The (b)(4) processes wheat and oats to a minimum temperature of (b)(4) for a (b)(4) as indicated in your process authority letter for the (b)(4). The (b)(4) process is a continuous process wheat and oats are continuously flowing through the (b)(4)

Your food safety plan for the (b)(4) at the (b)(4) states a monitoring interval time of (b)(4)

Your monitoring records for temperature are recorded in (b)(4) on the (b)(4) Temperature Read Out and is recorded in (b)(4) by the (b)(4) Operator on the (b)(4) Paperwork. The monitoring interval of (b)(4) at the (b)(4) does not ensure all product continuously processed in the (b)(4) reaches a lethal kill step to control the hazard of pathogens during the entire processing run.

While you state the temperature is continuously monitored and there is an audible alarm to indicate if temperatures fall below desired thresholds, there is no documentation of continuous monitoring of temperature in the (b)(4).

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Rohn R Robertson, Investigator
David M Amy, Investigator

X Rohn R Robertson
Investigator
Signed By: Rohn R. Robertson -S
Date Signed: 02-02-2024
08:57:48

DATE ISSUED
2/2/2024

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OBSERVATION 2

Your written sanitation preventive control procedures were not appropriate to significantly minimize or prevent the hazard requiring a preventive control.

Specifically,

- Your Master Sanitation Schedule is a (b)(4) including the (b)(4) Room. This plan does not control the hazard of recontamination from environmental pathogens within your processing equipment from under-processed product escaping the (b)(4) in the (b)(4) According to your Master Sanitation Schedule you clean the (b)(4) along with the rest of the entire facility (b)(4) .

In the "Root Cause Analysis for December 2023 Quaker Recall" you identified a proper cleaning frequency of the (b)(4) to be "(b)(4)

Your current practice of cleaning (b)(4) is not sufficient to control the hazard of recontamination from environmental pathogens within your processing equipment in the (b)(4) and was identified in the "Root Cause Analysis for December 2023 Quaker Recall" as partial causation for the event leading to your positive finished product sample for Salmonella Cubana. During your investigation into the root cause, you identified an accumulation of product in the (b)(4) which you identified as a harborage for salmonella.

- Your sanitation plan does not address control of personnel traffic, forklift traffic or the movement of equipment throughout your facility, specifically for the preventing traffic and the possible spread of pathogens from the (b)(4) and the silo area to the rest of your facility. The (b)(4) has several positive environmental swabs for Salmonella Cubana.

Additionally, FDA environmental sample 1234817 was positive for Salmonella Cubana. The positive sub-sample was collected in a hallway used by personnel and is outside of a processing room.

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- Your corrective actions in your sanitation plan do not identify and correct a problem that has occurred or reduce the likelihood that the problem will recur.

Specifically, you had an environmental positive on 09/07/23 for Salmonella Cubana. Your documentation of the corrective action includes procedures taken to clean and sanitize the affected area but does not include procedures taken to identify and correct the problem, reduce the likelihood that the problem will recur.

You had another environmental positive on 10/04/23 for Salmonella Cubana. Your documentation of the corrective action does not include procedures taken to identify and correct the problem, reduce the likelihood that the problem will recur.

Furthermore, there are no written corrective action procedures for environmental positives other than your (b)(4) Management stated each occurrence is unique and may be corrected differently.

Additionally, you had an event in 2021 of finished product Chewy Bars containing salmonella. You would not provide records documenting corrective actions taken for this event. On 11/27/23 you had another event of finished product lot "23H21K01 22" testing positive for Salmonella Cubana.

OBSERVATION 3

Your equipment and utensils were not designed and constructed to be adequately cleaned or maintained to protect against contamination.

Specifically, your processing equipment at the (b)(4) has a design flaw leading to possible harborage of under-processed product. Product flows from the (b)(4) to the (b)(4) Under processed product is removed from the

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system at the (b)(4)

The (b)(4) consists of moving parts (b)(4). The cooling chamber consists of (b)(4) to deflect particles and allow for more time in the cooling chamber. The cooling chamber creates harborage areas for under-processed material and pathogens within your system after the kill step.

Furthermore, you do not have any records of when a divert occurs. The cooling chamber is cleaned (b)(4) according to your Master Sanitation Schedule. This allows for a (b)(4) window of possible harborage of under processed product to stay in the system prior to the divert valve.

OBSERVATION 4

You did not implement your written supply-chain program.

Specifically, your supply chain control for mycotoxins in the raw material of wheat is not being implemented as the C of A you require from your supplier, to control mycotoxins, does not specifically mention anything about mycotoxins or any type of mycotoxins, or the testing/analysis of any type of mycotoxins in the receiving of wheat.

***DATES OF INSPECTION**

12/19/2023(Tue), 12/20/2023(Wed), 12/21/2023(Thu), 1/04/2024(Thu), 1/05/2024(Fri), 1/09/2024(Tue), 1/10/2024(Wed), 1/11/2024(Thu), 1/12/2024(Fri), 1/17/2024(Wed), 1/18/2024(Thu), 1/24/2024(Wed), 1/30/2024(Tue), 2/02/2024(Fri)

X David M Amy
Investigator
Signed By: David M. Amy III -S
Date Signed: 02-02-2024 08:58:18

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Rohn R Robertson, Investigator David M Amy, Investigator X Rohn R Robertson Investigator Signed By: Rohn R. Robertson -S Date Signed: 02-02-2024 08:57:48	2/2/2024

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."