February 23, 2024

Via email to orahafeast6firmresponses@fda.hhs.gov and Lauren.Crivellone@fda.hhs.gov

Lauren Crivellone
Compliance Officer
U.S. Food and Drug Administration
Office of Regulatory Affairs
Office of Human and Animal Food Operations East, Division 6
550 West Jackson Blvd, Room 1500
Chicago, IL 60661

Re: The Quaker Oats Co. – Response to Form FDA 483 Dated February 2, 2024 (FEI 1417217; 1703 E. Voorhees St., Danville, IL)

Dear Ms. Crivellone,

I am writing to respond to the Form FDA 483 (483) issued to our Danville, Illinois facility on February 2, 2024. The 483 was issued following an inspection conducted by the U.S. Food and Drug Administration (FDA) between December 19, 2023 and February 2, 2024. This inspection was initiated after we conducted a voluntary recall of granola products produced at the facility. We are providing a detailed response as Appendix 1 and a copy of the 483 as Appendix 2.

We stopped all food production in the Danville facility on December 21, 2023. We are committed to remaining shut down until we recommission the facility, reanalyze our Food Safety Plan, and take other appropriate steps to ensure the food we produce is safe. PepsiCo is committed to regulatory compliance and ongoing transparency and communication with FDA. We will not restart operations in the facility without notifying FDA and providing remediation documentation. We also will provide the agency with supplemental information regarding these 483 observations, where warranted, prior to restart.[1]

Food safety is a top priority for PepsiCo. We have robust global programs and quality management systems in place at our manufacturing facilities, with strong corporate and plant-level oversight and controls. However, in light of the Danville recall, we recognize that there are opportunities to enhance our food safety practices. We are conducting a comprehensive internal review to evaluate what events led to the recall and identify areas where we can strengthen our programs to further ensure food safety and quality.

[1] Additionally, we will take into account the agency's Discussion Points that were conveyed to us verbally during the inspection close out meeting.

If you have any questions about this submission or other matters, please contact me at Mike.Klein@pepsico.com.

Sincerely,

Mike Klein
Site Director
Quaker Danville, Illinois

cc: Arnab Sarkar, Ph.D, Sr. Director, North America Food Safety & Global Center of Excellence, PepsiCo R&D
Sarah Meyer, Vice President Quality & Food Safety, PepsiCo Foods North America
Harsha Ravindran, Director Quality & Food Safety, PepsiCo Foods North America
William Weissinger, Program Director, HAF East Division 6
Tamara Qtami, Director of Investigations Branch, HAF East Division 6
Lieutenant Commander Kelli Wilkinson, Director of Compliance Branch, HAF East Division 6

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Appendix 1: Detailed Response to Form FDA 483 Observations

Below we repeat the agency's observations in italics and then provide responses. A copy of the 483 is attached as Appendix 2.

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 the* (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) *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) *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) *.*

RESPONSE

Although the (b)(4) temperature was continuously monitored during operations prior to the recall and an alarm was in place to signal deviations, we acknowledge that the temperature was only recorded in (b)(4) and that exception events were not recorded. Any future use of (b)(4) equipment at the Danville facility will maintain use of continuous temperature monitoring, along with the new addition of a corresponding system that produces documentation that the system is operating within the validated operating parameters (including for deviations). We will provide the agency with documentation of these changes before restarting operations at the Danville facility using the flaker.

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) *cleaning schedule for the entire facility including the* (b)(4) *. 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* (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.

- *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.

RESPONSE

(b)(4) Sanitation

We acknowledge that, upon review, the routine sanitation practices in place for the (b)(4) equipment, including the frequency of sanitation, need to be improved. We will provide the agency with documentation of these sanitation program changes before restarting operations using the (b)(4) at the Danville facility.

It is important to clarify, however, that while the entire facility operates according to a (b)(4) cleaning schedule, this does not mean that cleaning only occurred every (b)(4) for all equipment. This facility implements cleaning at various frequencies depending on the nature of the equipment.

Hygienic Zoning

With respect to the observation regarding the movement of personnel and equipment, we will evaluate traffic flow and implement hygienic zoning prior to resuming operations in this facility.

Pathogen Environmental Monitoring (PEM) Program

As part of reanalyzing our Food Safety Plan, we will review our PEM program to ensure it includes procedures for both the execution and documentation of root cause analyses following positive PEM results. Under our current program, each PEM positive is investigated, vectored, and localized corrective actions are taken (e.g., floor repairs; sanitation changes). However, we acknowledge that there are further opportunities, such as using root cause investigation tools (e.g., fishbone) to help identify and correct the problem and reduce the likelihood that the problem will recur, and analyzing trends as a way to evaluate the efficacy of corrective actions. The revised program will include enhanced procedures and documentation regarding corrective actions to ensure that we take appropriate action for environmental monitoring positive results.

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) Under processed product is removed from the system at the (b)(4).*
>
> *The (b)(4) rollers consists of moving parts (b)(4) The cooling chamber consists of (b)(4) 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 (b)(4).*

RESPONSE

We acknowledge that there were gaps in the (b)(4) divert system for the thermal process, which is activated during startup and changeovers. We are evaluating approaches to modify this system if we resume use of the (b)(4) at the facility, including using a combination of timing and recirculation to prevent downstream contamination and completing run time studies to scientifically define appropriate run times with a combination of intermittent and extensive cleaning. Additionally, we are considering design and product flow changes to the equipment that will improve raw to RTE segregation. We will provide the agency with documentation of these changes before restarting Danville (b)(4) operations, which have their own unique design.

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.

RESPONSE

PepsiCo has implemented a robust program at the corporate level to manage supply-chain applied preventive controls, such as the hazard of mycotoxins in raw wheat. In response to this observation, as explained below, we reviewed the regulatory and program requirements for this hazard and confirmed that we are compliant with 21 CFR Part 117, Subpart G, and are following our own process. We believe there may be a misunderstanding here, as our program does not require a Certificate of Analysis from the supplier for the hazard of mycotoxins in raw wheat.

Deoxynivalenol (DON) is a regional, seasonal, and temporal field and storage contaminant for wheat. FDA has established a guidance level of 1 ppm for DON in wheat destined for human consumption.[2] Historically, recalls related to mycotoxins have been classified as Class II. Therefore, PepsiCo identifies DON as a "hazard requiring a preventive control" (HRPC) and considers DON a non-SAHCODHA[3] HRPC.

Our corporate-level supply chain program document establishes the following verification requirements where a supplier controls an HRPC:[4]

[2] *Guidance for Industry and FDA: Advisory Levels for Deoxynivalenol (DON) in Finished Wheat Products for Human Consumption and Grains and Grain By-Products used for Animal Feed* (July 2010).
[3] "Serious adverse health consequences or death to humans or animals" (i.e., Class I recall equivalent).
[4] PepsiCo Supply Chain Program, Version 3, June 6, 2023. This document was provided to FDA as part of the inspection.

Table 1: HRPC Verification Activity

Type of Verification Activity	Specific Activity	Frequency
Review of the supplier's relevant food safety records	Review of supplier's HACCP or FSP and Process Flow Chart (identifying where hazard is controlled)	(b)(4)
"Other" appropriate supplier verification activities	Completion of PepsiCo's Pre-screen Survey (new supplier site) or Re-Approval Questionnaire (existing supplier site)	(b)(4)
"Other" appropriate supplier verification activities	Appropriate Food Safety certification audits have been performed and corrective actions for any critical findings completed	(b)(4)
Testing	COA verification	(b)(4) (b)(4)

Further, the program provides: "Based on its experience, the PepsiCo team has determined that **for each ingredient where the supplier controls a SAHCODHA hazard**, the supplier must be subject to a periodic onsite audit that proves its certification to a supplier auditing scheme (e.g. GFSI, AIBI, Global GAP, etc.), and **the supplier must conduct testing using an approved PepsiCo method and supply PepsiCo with a lot-by-lot Certificate of Analysis (COA) as a verification activity**." (emphasis added). Also of relevance here is the provision that explains: "**Where the hazard analysis determines that a supplier of raw/agricultural material is controlling a hazard, a case-by-case verification plan is implemented**" (emphasis added). Taken together, it is clear that our corporate-level program does not require lot-by-lot certificates of analysis for a non-SAHCODHA hazard (mycotoxins) in a raw agricultural material (wheat).

The Danville facility's Food Safety Plan addresses the mycotoxin risk to wheat specifically and the ingredient hazard analysis includes the potential for exposure to DON in wheat ingredients, identifying the need for a supply-chain applied preventive control:

PV Code	Ingredient Name	Hazard Category	Potential Hazard	Severity 1 - 6 (Risk Level)	Frequency [upon receipt] (1 - 5)	Risk Score (Severity x Frequency)	Hazard requires a FSMA preventive control? (No/Yes)	Hazard requires a FSMA preventive control? Comments	Comments on Frequency Decision	Control Measures (Supplier)	Control Measures (Plant)	Control Measures (Corporate)
(b)(4)		Chemical - Contaminant	Mycotoxin (Deoxynivalenol (DON) (a.k.a. vomitoxin))	3	2	(b)(4)	Yes	Supplier	Has been known to occur.	Raw material quality program; GAPs; GMPs; Monitoring Program	None	Review supplier Monitoring Program & results

Our specification for this ingredient is where we document our specific verification requirements for this supply-chain applied preventive control, establishing that there is no lot-by-lot COA requirement for this ingredient:

PepsiCo Ingredient Specification
Confidential and Proprietary Information - Do Not Duplicate

Ingredient Code:	Ingredient Name:	Status:
(b)(4) (b)(4)	RED WHEAT, CLEANED	Approved

Revision #:	Issue Date:
00.0	09-Apr-2020

III. Physical/Chemical Parameters

Parameter	Test Method(s)	Target	Min	Max	Supplier Test Frequency	Required on COA
[1] Deoxynivalenol (b)(4)	(b)(4)			(b)(4)	Upon Request	No

We have a number of verification activities for this supplier in our files, including evaluating their process to manage for the presence of DON, requiring a supplier questionnaire regarding their food safety programs, and reviewing a third-party audit report. In particular, we have verified that this supplier has a program in place to test every incoming load for DON at the (b)(4) level. As determined to be appropriate based on our risk evaluation, we receive periodic testing results from this supplier, rather than requiring a lot-by-lot COA.