Since 1897

January 28, 2020

U.S. Customshouse Room
Room 900
200 Chestnut Street
Philadelphia, PA 19106
Attn: Mr. Sean D. Duke, Investigator

Via Email orahafeast2firmresponses@fda.hhs.gov

RE: FDA Form 483 Issued to The J.M. Smucker Company, Bloomsburg, PA (FEI 3004291002) on January 9, 2020

On behalf of The J.M. Smucker Company, I am writing in response to the Form FDA 483 Inspectional Observations (483) issued by the U.S. Food and Drug Administration (FDA) on January 9, 2020, following FDA's inspection of our facility located in Bloomsburg, PA (Bloomsburg) on 12/16/2019 – 1/9/2020. We are providing our response within 15 business days of receipt of the 483, consistent with FDA policy.

Observation 1

You did not identify and implement preventative controls to ensure that any hazards requiring a preventive control are significantly minimized or prevented.

This is a repeat observation from the previous inspection conducted on 03/15/2019.

Specifically, you did not implement Preventative Controls outlined in your Food Safety Plan for the Hazard: Nutrient Toxicity, which you identified as a hazard requiring a Process Control for your canned cat and dog foods you produced, which includes Special Kitty brand Mixed Grill Plate lot #92630830B on 09/20/2019.

Response:

Regarding the root cause of our 12/4/2019 recall for the Special Kitty Mixed Grill Pate lot 9263803B packed on 9/20/2019, as reported via our updated Attachment B to FDA on 12/12/19, our investigation, (b) (4) [redacted]

(b) (4) [redacted].

We respectfully disagree that the (b) (4) [redacted] was a hazard requiring a preventive control and, accordingly, that this is a repeat observation. The observation says, "Specifically, you did not implement Preventive Controls outlined in your Food Safety Plan for the Hazard: Nutrient Toxicity, which you identified as a hazard requiring a Process Control for your canned you produced, which includes Special Kitty brand Mixed Grille Pate lot # 9263083-B on 9/20/2019." This appears to be a reference to "nutrient toxicity" listed as a hazard requiring a preventive control in the Food Safety Plan under "Micro and Hand Add Weighing." (b) (4) [redacted]." As explained above, the facility has concluded that the (b) (4) [redacted] is not a hazard requiring a preventative control.

This specific hazard was not addressed in the Food Safety Plan because we considered an event of this sort to be very unlikely to occur. Under 21 C.F.R. § 507.33, our hazard analysis "must include an evaluation of the" identified hazards "to assess the severity of the illness or injury to human or animals if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls." We concluded that a preventive control was not required for the (b) (4) [redacted] to pet food formulas because, while this hazard could, in an extreme case, cause a serious adverse health effect, the hazard is very unlikely to occur. Specifically, given that it takes several steps even to operate the (b) (4) [redacted] equipment, including that the operator must (b) (4) [redacted], we considered it to be extremely unlikely that an operator would inadvertently do so, particularly in lieu of (b) (4) [redacted], as happened here, and especially at levels high enough to cause serious adverse effects. The plant had no history of such incidents prior to September 20, 2019. Accordingly, because the probability this hazard would occur in the absence of a preventive control was so low, we did not conclude that it was a hazard requiring a preventive control.

Nonetheless, we took immediate corrective actions to prevent recurrence, including (b) (4) [redacted]. Now, when a product recipe requires the (b) (4) [redacted]. Also, we will, within a reasonable timeframe,

revisit and review our Food Safety Plan with a particular focus on the potential for nutrient toxicities, even those we had not deemed to be hazards requiring a preventative control.

Observation 2

Your process controls did not include procedures, practices, and/or processes that ensure the control of parameters during operations to significantly minimize or prevent hazards.

This is a repeat observation from the previous inspection conducted on 03/15/2019.

Specifically, the previous inspection found that you (b) (4) The validation you supplied documented that it was performed by (b) (4). However, your procedure for monitoring the operation of the (b) (4)

Response:

The plant has updated the (b) (4) check monitoring practices to ensure that the (b) (4) checks validation process. The written operational procedures for (b) checks/monitoring have been updated and reviewed with relevant plant personnel via appropriate document change management controls. Finally, we have completed training and documentation for these activities as of the date of this response, as well.

Observation 3

You did not verify that your preventive control(s) are consistently implemented and effective by other activities appropriate for verification of implementation and effectiveness.

This is a repeat observation from the previous inspection conducted on 03/15/2019.

Specifically, the previous inspection found that you perform "Mixer Coefficiency Studies to verify the mixing effectiveness of your premix and major batch mixers. The records you provided during that inspection documented that the testing result for the premix mixer was approximately (b) (4)

Response:

The plant has completed a mixer effectiveness study for the Premix Mixers of the date of this response and documented the results of the study. (b) (4)

We hope that FDA agrees that these actions adequately address the Agency's observations. If we can provide further information, please do not hesitate to contact us.

Sincerely,

Allen Tart

Allen Tart
Senior Director, Pet Operations