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May 23, 2019

Danial S. Hutchison
Compliance Officer
FDA Kansas City District
Office of Human and Animal Foods – Division II West
U.S. Food and Drug Administration
8050 Marshall Drive, Suite 205
Lenexa, KS 66214

Re: Hill's Pet Nutrition, Inc., Topeka, KS (FEI 1912875) – 75 Day Update to 483 Response

Dear Mr. Hutchison:

On behalf of Hill's Pet Nutrition, Inc. ("Hill's" or "HPN"), we are writing to provide an update regarding the corrective actions we have implemented at our Topeka, Kansas ("Topeka") facility following our recall of select canned dog food products for elevated vitamin D. This letter follows up on our March 12, 2019 response to the FDA Form 483 ("483") issued to the Topeka facility on February 19, 2019, in which we committed to providing an update to FDA within 75 days regarding our progress implementing corrective actions.

In addition to the corrective actions identified in our 483 response, we also have implemented corrective actions in response to our March 20, 2019 expansion of the recall to cover an additional eight SKUs of canned dog food.[1] These products contained the same vitamin premix that resulted in the January 31, 2019 recall and were identified through additional product testing Hill's undertook following the initial recall to ensure we had taken all appropriate action. We discuss our Food Safety Plan ("FSP") reanalysis and corrective actions that followed this incident in our response below.

[1] As you know, we also recently clarified that a single can date/lot code within an already recalled case of dog food was inadvertently omitted from our recall list. This relates to the same vitamin premix that led to the Jan. 31 voluntary recall.

We are pleased to report that we have completed all of the corrective actions identified in our 483 response addressing the recall and FDA's inspection. We are, of course, disappointed that this event happened and are making every effort to learn from this experience. We are confident that the enhancements we have made to our programs will help significantly minimize the risks to our products going forward. We look forward to discussing our progress with you and answering any questions the agency may have at our meeting on May 29, 2019.

In the discussion that follows, we provide updates regarding our root cause analysis and FSP revisions, ongoing engagement with and oversight of our vitamin premix supplier (b) (4) and other company-wide efforts to learn from this experience. Following these updates, we provide a summary chart that includes status updates on each of our corrective actions that were in progress at the time of our 483 response or that we are implementing in response to the recall expansion.

Root Cause Analysis and Food Safety Plan Revisions

We have completed reanalysis of our FSP as required under 21 CFR § 507.50(b), and as a result, have made modifications to enhance the plan. (b) (4) These revisions are closely tied to our root cause analysis, which we will discuss at our upcoming meeting.

First, in light of (b) (4) misformulation error involving the vitamin D ingredient in the vitamin premix, we have enhanced our supply chain program. Our revised FSP clarifies the explanation of our supply-chain-applied controls ("SCACs") to describe how they fit into our overall food safety program. As discussed in our 483 response, we also implemented additional verification activities for our vitamin premix and trace mineral premix suppliers, by requiring (b) (4) COAs for these ingredients.[2] We now require and receive such (b) (4) COAs for (b) (4) incoming shipment of vitamin and trace mineral premixes at our Topeka facility. We have integrated the requirement for (b) (4) COAs into our plant-level receiving procedures and internal (b) (4) system, requiring a positive release of vitamin and trace mineral premixes into our facility based on an accompanying COA confirming the premix meets our specifications.

Second, while working with (b) (4) to address the root cause of their misformulation error, we identified opportunities to strengthen our own procedures in ways that could prevent the same misformulation problem from happening. We are now implementing a process preventive control related to the misformulation hazard for our (b) (4) in our Topeka manufacturing facility. We also want to have additional controls in place in our operation to avoid the potential for the same error to occur when we engage in similar (b) (4) activities involving vitamins and trace minerals.

[2] As noted in our 483 response, (b) (4) program due to ongoing work to validate an appropriate test method. This work will be completed by (b) (4).

Our FSP has been updated to reflect the results of this reanalysis, and we also have developed corresponding Standard Operating Procedures ("SOPs"), where appropriate. The revised FSP was implemented on (b) (4) and is provided in Appendix 1.A, with the material revisions highlighted in yellow. A summary of our FSP reanalysis is provided in Appendix 1.B.

Supplier Oversight of (b) (4)

We have been in continuous contact with (b) (4) since we learned of their misformulation error that triggered our recall. We have made (b) (4) that manufactured the affected lot of vitamin premix, as follows:

- On (b) (4), Hill's made a site visit to discuss (b) (4) root cause analysis investigation. (b) (4) stated that the misformulation was caused by human operator error and failure of human secondary review. They further stated that new processes have been implemented, including (b) (4), to avoid any possible repeat of this error.

- On (b) (4), Hill's made a second site visit to ensure (b) (4) was appropriately implementing the programs identified during the (b) (4) visit to prevent future misformulation events. In particular, Hill's discussed the need for (b) (4) to implement a preventive control to significantly minimize or prevent the misformulation hazard.

- On (b) (4) Hill's performed (b) (4). (b) (4) stated that they intend to implement a process preventive control to significantly minimize or prevent the hazard of Vitamin D misformulation, but that they had not yet completed development of the supporting programs. (b) (4) also was still reviewing the potential to implement a preventive control for other vitamin ingredients.

We are closely tracking (b) (4) corrective actions. After our (b) (4) visit, we initiated telephone conferences with (b) (4) (and sometimes (b) (4)) to stay abreast of their progress reanalyzing their FSP and developing a process preventive control for misformulation. After their new programs are in place, we will monitor their implementation on an ongoing basis. In particular, we will (b) (4). We consider this to be ongoing supplier verification, rather than a corrective action linked directly to the recall event.

Although (b) (4) continues to supply us with premixes while this work is underway, we are confident that the premixes are appropriately formulated because they now are accompanied by (b) (4) COAs that demonstrate the premixes meet our specifications. Longer term, however, we recognize that it is essential for (b) (4) to have appropriate preventive programs in place to ensure the premixes are properly formulated.

Summaries of our site visits and audit of (b) (4) are provided in Appendix 1.C. An example of a (b) (4) COA from (b) (4) is provided in Appendix 1.E.[3]

Food Safety Culture

Hill's is committed to instilling an even stronger food safety culture. In addition to implementing specific corrective actions in response to this incident, we continue to take a big picture look at whether there are other proactive steps we can take across our company to strengthen our programs. For example, now that we have completed our FSP reanalysis at Topeka, (b) (4) .[4] As another example, in (b) (4) meeting for our Plant Managers, Quality Managers, Procurement, Science and Technology, Corporate Quality and Food Safety, Corporate Operations, Regulatory, and Legal teams (approximately (b) (4) people) to provide continuing education (b) (4) . This provided an excellent opportunity for cross-functional collaboration and was helpful to reinforce our commitment to continuous improvement. We will continue to seek out such opportunities.

Summary of Progress on Outstanding Corrective Actions from 483 Response

In our 483 response, we committed that several corrective actions would be completed before this update. We have now completed those commitments. On the chart below, we provide a summary of each of these corrective actions and an update on our progress.

Corrective Action	Update
Train employees on Interim Receiving Procedure	**Complete.** As committed to in our response, we trained employees on the Interim Receiving Procedures on (b) (4) . Documentation of the training is provided at Appendix 1.D.
Implement new (b) (4) Certificate of Analysis (COA) requirement for vitamin premixes and trace mineral premixes	**Complete.** We were receiving (b) (4) COAs from both of our vitamin premix and trace mineral premix suppliers by (b) (4) , consistent with the commitment in our 483 response. Examples of (b) (4) COAs from our two premix suppliers are provided in Appendix 1.E (b) (4)) and Appendix 1.F (b) (4) .

[3] Our specification provides a target range for the levels of vitamins in the premixes. Accordingly, it is acceptable for the "%claim" reported on the COA to not be at "100%" so long as the levels are within our specification. The levels established in our specifications are based on (b) (4) of the finished product in which the premix will be used. The same approach applies to the mineral premixes.

[4] (b) (4) .

Revise Receiving Procedure to address the need for (b) (4) COAs for (b) (4) lot	**Complete.** Our revised Receiving SOP is provided at Appendix 1.G. This procedure was implemented by (b) (4), consistent with the commitment in our 483 response.[5]
Train personnel on revised Receiving Procedure	**Complete.** Personnel at Topeka were trained on the new receiving procedures on (b) (4). Documentation of the training is provided at Appendix 1.H and Appendix 1.I.
Integrate COA requirement into our internal system (b) (4) so that incoming vitamin and trace mineral premix ingredients cannot be received without conforming COAs	**Complete.** Our integration of the (b) (4) COA requirement into our (b) (4) system occurred by (b) (4), consistent with the commitment in our 483 response. See Appendix 1.J (work instruction).
Conduct onsite audit of (b) (4)	**Complete.** We have visited (b) (4) since the recall, including (b) (4) visit to perform an on-site audit for purposes of supplier verification. We also remain in close contact with (b) (4) to monitor their corrective actions, including (b) (4) calls with their team. A summary of our visits and audit is provided at Appendix 1.C.
Revise Food Safety Plan to reflect modifications based on corrective actions and reanalysis	**Complete.** We engaged in reanalysis of our Food Safety Plan and made modifications that include: ● Reviewing and updating the hazard analysis for all plant processes; ● Updating the ingredient hazard analyses for our vitamin premix and trace mineral premix ingredients (b) (4) ● Clarifying the explanation of our supply-chain-applied controls; ● Implementing additional verification activities for our vitamin premix, trace mineral premix, and tuna suppliers; and ● Implementing a process preventive control for the (b) (4) steps to enhance control of the misformulation hazard. We implemented the revised Food Safety Plan on (b) (4) The revised Food Safety Plan is provided at Appendix 1.A.

[5] Note that for some programs and procedures, such as this receiving procedure, implementation occurred (b) (4).

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In closing, we are pleased to share our progress implementing corrective actions and are confident that the changes we have made will further enhance the safety of our products. If you have any questions or require any further information, please do not hesitate to contact us.

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(b) (4)

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