WARNING LETTER

Hill's Pet Nutrition Inc.

MARCS-CMS 576564 — NOVEMBER 20, 2019

Delivery Method:

VIA UNITED PARCEL SERVICE

Product:

Animal & Veterinary

Recipient:

Peter Brons-Poulsen

President and CEO

Hill's Pet Nutrition Inc.

400 SW 8th Ave.
Topeka, KS 66603
United States

Issuing Office:

Office of Human and Animal Foods Division II West

United States

913-495-5100

Dear Mr. Brons-Poulsen:

The U.S. Food and Drug Administration (FDA) conducted inspections of your pet food manufacturing facility located at 320 NE Crane St., Topeka, Kansas on February 1 through February 19, 2019 and March 25 through 27, 2019. These inspections were conducted in response to a Reportable Food Registry report (RFR) event (EON-378261) filed by your firm and in response to your recall of products marketed with toxic levels of vitamin D. FDA also conducted a complaint investigation from February 11 through February 12, 2019, during which FDA obtained samples of your canned dog food.

The inspections and the investigation confirmed that animal food products with unsafe levels of vitamin D were manufactured and marketed by your firm. You determined the unsafe levels of vitamin D were the result of an ingredient that you received and accepted in a manner not in accordance with your receiving procedures, and that was subsequently incorporated in the animal food products. The unsafe amounts of vitamin D cause your products listed below to be adulterated because they bear or contain a food additive that is unsafe within the meaning of the Federal Food, Drug, and Cosmetic Act (FD&C Act).[1]

Furthermore, the inspection revealed violations of FDA's Hazard Analysis and Risk-Based Preventive Controls requirements for animal food found in Title 21 of the Code of Federal Regulations, part 507, subpart C (21 CFR part 507, subpart C). This causes your products to be adulterated within the meaning of the FD&C Act.[2]

The introduction or delivery for introduction into interstate commerce of any food that is adulterated is a prohibited act under the FD&C Act.[3] Furthermore, the failure to follow the hazard analysis and risk-based preventive controls requirements is also a prohibited act under the FD&C Act.[4] You may find the Federal Food, Drug, and Cosmetic Act and FDA's regulations through links on the FDA's website at www.fda.gov (http://www.fda.gov).

At the close of the February 1 through February 19, 2019 inspection, you were issued a Form FDA 483, Inspectional Observations. We received your written responses dated March 12, 2019, May 23, 2019 and August 30, 2019. We have reviewed your responses and we discuss your violations and your corrective actions below.

We acknowledge that your firm initiated several voluntary recalls for excessive amounts of vitamin D in various finished products. On January 31, 2019 your firm initiated a recall (RES# 82018) of twenty-five (25) different canned dog food products manufactured by your firm. On March 20, 2019 your firm determined that additional products were affected. As a result, approximately twenty (20) additional lots of product previously listed in the original recall were added, and the recall was expanded to include eight (8) new products of canned dog food. On May 20, 2019 your recall was expanded yet again to include an additional lot. A comprehensive list of your recalled products can be found on FDA's website at www.fda.gov (http://www.fda.gov).

Adulterated Animal Food - Unapproved Food Additive

On February 11 and 12, 2019, during a complaint investigation, FDA collected for vitamin D analysis two samples of your Hills Prescription Diet Digestive Care i/d Low Fat (SKU Number 10423) canned dog food. These samples were part of the lots covered by your recall. Testing of the products revealed the following results:

- Lot code BEST BEFORE 10 2020, T1911124 3912, found 100,170 to 107,282 IU/kg of vitamin D in your canned dog food.
- Lot code BEST BEFORE 10 2020, T1911125 3912, found 102,829 to 102,346 IU/kg of vitamin D in your canned dog food.

A food additive is a substance that becomes a component of food unless it is generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures to be safe under the conditions of its intended use.[5] According to scientific literature reviewed and summarized by scientific committees in the National Research Council, and the 2017 Official Publication of the Association of American Feed Control Officials on pages 149-162, vitamin D in dog food is safe in the amount of 500 to 3,000 IU/kg.[7] According to the scientific literature, concentrations of vitamin D in dog food above 4,000 IU/kg dry matter cause signs of vitamin D toxicosis, with severity of signs increasing with increasing concentrations of the vitamin.[7] Although vitamin D is an essential nutrient that allows dogs to regulate the balance and retention of calcium and phosphorus, when high levels of vitamin D are consumed, excessive amounts are not excreted but are stored in fat tissue and the liver. The adverse health consequences from consuming excessive levels of vitamin D can lead to kidney failure and even death.[8]

The above-referenced dog food samples contained vitamin D at levels in excess of 33 times the recommended safe upper limit. At these levels, vitamin D is not generally recognized as safe; therefore, it is a food additive. Under section 409 of the Act (21 U.S.C. § 348), a food additive is unsafe unless a regulation is in effect that prescribes the conditions under which the additive may be safely used, and the additive and its use or intended use are in conformity with that regulation. We are not aware of any regulation that would allow the use of vitamin D at the levels found in the above-referenced canned dog food. Therefore, the vitamin D is an unsafe food additive and the canned dog food containing these elevated levels of vitamin D is adulterated under section 402(a)(2)(C)(i) of the FD&C Act [21 U.S.C. § 342(a)(2)(C)(i)].

Adulterated Animal Food - Hazard Analysis and Risk-Based Preventive Controls Requirements

During our inspection of your facility, FDA Investigators noted violations of the Hazard Analysis and Risk- Based Preventive Controls requirements for animal food found in Title 21 of the Code of Federal Regulations, part 507, subpart C (21 CFR part 507, subpart C). These violations render your animal food products adulterated under the FD&C Act.[9] Violations observed during the inspection include, but are not limited to, the following:

Your firm did not sufficiently assess the probability that a vitamin D toxicity or deficiency hazard will occur in the absence of a preventive control as required by 21 CFR 507.33(c)(1).

Specifically, your firm uses vitamin premix in the manufacture of animal food products, but your firm failed to implement your prerequisite program to ensure that the vitamin premix did not contain an excess of vitamin D, which is a known or reasonably foreseeable hazard that could occur in the absence of a preventive control. As stated in your food safety plan's risk assessment matrix for your vitamin premix, you were relying on a **(b)(4)** to prevent nutrient deficiencies and toxicity hazards **(b)(4)**, which you classified as a high risk chemical hazard. You noted that "[i]f the raw materials or other ingredients do not contain nutrients at the expected levels, this may result in either a nutrient deficiency or toxicity hazard when the ingredient is incorporated into

the animal food based on a preset formulation." Your food safety plan also stated that "[c]hemical hazards identified as high risk require the hazard be analyzed and be within acceptable limits prior to unloading the specific raw material into the manufacturing facility."

However, the vitamin premix was not analyzed and subsequently reviewed to ensure that the vitamin D added to final products from the premix would meet your firm's pre-set formulation. Your ingredient specification for the vitamin premix included a target specification for vitamin D and states that the "Supplier must include Certificate of Analysis **(b)(4)**," but your firm did not obtain Certificates of Analysis (COA) upon receipt **(b)(4)** of vitamin premix from your supplier. Your firm also failed to test, evaluate against your specification, and subsequently reject the vitamin premix containing excess vitamin D, as required by your food safety plan. As a result, you used vitamin premix containing a concentration of vitamin D that was outside your specification.

As a result of your failure to follow your food safety plan, the hazard of vitamin D toxicity was not adequately managed at your receiving step. Therefore, you did not reduce the probability that the hazard would occur in the absence of a preventive control. As a result of your failure to consistently implement your pre-requisite program, a systematic failure of your food safety plan occurred that resulted in the recall of canned dog food as identified above. The systematic failure also resulted in adulterated animal food, as described above.

Corrective Actions

We acknowledge your promised corrective actions in your written responses dated March 12, 2019, May 23, 2019, and August 30, 2019 to the Form FDA 483, which include implementing a **(b)(4)** Certificate of Analysis (COA) requirement for vitamin premixes and trace mineral premixes, revising the Receiving Procedure to address the need for **(b)(4)** COAs **(b)(4)**, training personnel on the revised Receiving Procedure, integrating COA requirements into an internal system so that incoming vitamin and trace mineral premix ingredients cannot be received without conforming COAs, conducting an onsite audit of your supplier's facility, revising your Food Safety Plan, and implementing a process preventive control for the **(b)(4)** steps to enhance control of the misformulation hazard.

We are unable to assess the adequacy of your corrective actions because many are preexisting procedures that were not followed consistently prior to the recall event. For example, your requirement for vitamin premixes with vitamin D to have a COA **(b)(4)** was documented in your ingredient specification before the recall. This was further confirmed by your firm's special instructions to your supplier **(b)(4)**. In your response to the Form FDA 483, you stated that your food safety plan was not intended to cover "misformulation" by your supplier. **(b)(4)** and noted that "[n]utrient deficiency or toxicity hazards can be the result of incorrect levels of nutrients in incoming raw materials or ingredients."

Your response states that your firm is now implementing a process preventive control at the **(b)(4)** step; however, you did not provide adequate documentation demonstrating the implementation and effectiveness of the preventive control to include the associated management components as required by 21 CFR 507.39 and therefore we are unable to determine the adequacy of this corrective action.

The corrective action of a "process preventive control" at your **(b)(4)** step **(b)(4)**. However, it does not address the root cause of this incident, which was accepting an ingredient without confirming that it contained vitamin levels that were within specification as required by your procedures.

FDA will verify your proposed voluntary corrective actions during a future inspection of your firm.

Conclusions

The violations cited in this letter are not intended to be an all-inclusive list of violations that exist at your facility. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure your firm complies with all requirements of federal law, including FDA regulations. You should take prompt action to correct the violation cited in this letter. Failure to promptly correct this violation may result in legal action without further notice, including, without limitation, seizure and injunction.

- For more information on the Current Good Manufacturing Practice requirements of 21 CFR part 507, subpart B please see FDA's Guidance for Industry #235, Current Good Manufacturing Practice Requirements for Food for Animals, at:

https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM499200.pdf (https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndu).

- For more information on the Hazard Analysis and Risk-based Preventive Controls requirements of 21 CFR part 507, subparts C and E please see FDA's draft Guidance for Industry #245, Hazard Analysis and Risk-Based Preventive Controls for Food for Animals, at: https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM592870.pdf (https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforI).

Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time frame within which you will complete the correction. If you do not believe that your products are in violation of the FD&C Act, include your reasoning and any supporting information for our consideration.

Section 743 of the FD&C Act [21 U.S.C. § 379j-31] authorizes FDA to assess and collect fees to cover FDA's costs for certain activities, including reinspection-related costs. A reinspection is one or more inspections conducted subsequent to an inspection that identified non-compliance materially related to a food safety requirement of the FD&C Act, specifically to determine whether compliance has been achieved. Reinspection-related costs means all expenses, including administrative expenses incurred in connection with FDA's arranging, conducting, and evaluating the results of the reinspection and assessing and collecting the reinspection fees [21 U.S.C. § 379j-31(a)(2)(B)]. For a domestic facility, FDA will assess and collect fees for reinspection-related costs from the responsible party for the domestic facility. The inspection noted in this letter identified non-compliance materially related to a food safety requirement of the FD&C Act. Accordingly, FDA may assess fees to cover any reinspection-related costs.

Your firm's response should be sent to Danial S. Hutchison, Compliance Officer, 8050 Marshall Drive, Suite 205, Lenexa, Kansas 66214. If you have any questions about this letter, please contact Compliance Officer Hutchison at (913) 495-5154 or Danial.Hutchison@fda.hhs.gov (mailto:Danial.Hutchison@fda.hhs.gov).

Sincerely,
/S/
Cheryl A Bigham District Director
Program Division Director
Office of Human and Animal Foods Division II West

1. Section 402(a)(2)(C)(i) of the FD&C Act [21 U.S.C. § 342(a)(2)(C)(i)] and section 409 of the FD&C Act [21 U.S.C. § 348].
2. Section 402(a)(4) FD&C Act [21 U.S.C § 342(a)(4)] and 21 CFR 507.1(a)(1).
3. Section 301(a) of the FD&C Act [21 U.S.C. § 331(a)].
4. Section 301(uu) of the FD&C Act [21 U.S.C. § 331(uu)].
5. See definition of "food additive" in Section 201(s) of the FD&C Act [21 U.S.C § 321(s)]. There are specific listed exceptions to the definition of food additive, but those exceptions do not apply to the use of vitamin D in animal food.
7. [a. b.] The most recent publication contains the same range for recommended vitamin D concentration in dog food based on dry matter. Association of American Feed Control Officials. 2019. "AAFCO Dog Food Nutrient Profiles" pp 153-166.
8. Food and Drug Administration. 2019. "Vitamin D Toxicity in Dogs." Accessed November 4, 2019. https://www.fda.gov/animal-veterinary/animal-health-literacy/vitamin-d-toxicity-dogs.
9. Section 402(a)(4) of the FD&C Act [21 U.S.C. § 342(a)(4)] and 21 CFR 507.1(a)(1).

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