DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

July 15, 2015

Dr. Roberta Krauss Wyde
Mr. Richard S. Wyde
(b) (6)
[redacted]

RE: Docket No. FDA-2006-P-0276 (previously 2006P-0126/CP1)

Dear Dr. and Mr. Wyde:

This letter responds to the citizen petition (FDA-2006-P-0276) you submitted to the Food and Drug Administration (FDA) on March 17, 2006. (b) (6) [redacted]

I understand that you resolved your dispute with S&M Nu-Tec, L.L.C.,[1] and notified the agency, by e-mail dated April 30, 2006, that you would not be participating further in the FDA proceeding initiated by your citizen petition, but that you did not agree to withdraw your petition.

Your petition requests that FDA take the following actions:

> "1. Initiate a formal investigation of and scientific research concerning the risks of injury or death that can result from ingestion of Greenies by dogs.
>
> 2. Due to the underreporting by S&M and by individuals in the general public of harms caused by Greenies, conduct a survey of all veterinarians in the United States about their experiences with harms caused by Greenies to dogs.
>
> 3. Depending on the results of such a survey, create an active surveillance system to gather the incidence of Greenie related injuries and deaths.
>
> 4. Request S&M to recall all Greenies or order such a recall pending completion of the survey and investigation requested in this petition.
>
> 5. Initiate a seizure of all Greenies from retailers and veterinarian offices if S&M will not issue a company recall of the product.
>
> 6. Initiate a formal investigation into and research of the color additive included in Greenies.

[1] In May 2006, Mars Inc. acquired the Greenies line of products.

7. Publish a notice of this petition in the Federal Register and invite comments from interested persons.

8. Conduct a hearing or hearings under 21 C.F.R. Parts 13, 14, 15 and /or 16, as applicable, at which interested parties can present evidence relevant to the claims in this petition.

9. Require a correction in the Greenies' packaging and labeling to apprise consumers of the risks and dangers to their dogs associated with ingesting Greenies.

10. If the Agency determines that the Greenies formula and manufacturing process can or do create a risk of harm to dogs from their ingestion, order corrections to the formula and/or and (sic) the manufacturing process.

11. Require S&M to change its sales techniques to disclose to veterinarians, distributors and retailers accurate facts about the extent of the risks to dogs from ingesting Greenies.

12. Order disclosure by S&M of, and publish for public consumption, all studies it has conducted related to the potential negative effects on dogs from ingesting Greenies.

13. Initiate an investigation into the thoroughness of the research conducted for the endorsement of Greenies by the Veterinary Oral Health Council ("VOHC"), which is a group of veterinarians that issued a certificate of approval on which the public relies for its decisions to purchase this potentially dangerous product.

14. Order payment of damages to owners of dogs determined to be harmed by Greenies, using some of the $340 million in revenues earned by S&M in 2005 from the sale of Greenies as the basis of a constructive trust for these payments.

15. Fine S&M to the maximum extent permitted under applicable regulations if it is found to have failed to disclose material facts associated with Greenies or violated any regulations or statutes under the jurisdiction of the Commissioner.

16. Based on information obtained pursuant to Petitioners' other requested Agency actions, and if appropriate, pursue applicable remedies and procedures in accordance with 21 C.F.R. pt. 7, subpt. E."

We have considered your petition, and for the reasons explained below, we are denying your petition under 21 CFR § 10.30.

We note that your requests generally fall within the following categories: requests for the Agency to investigate the safety of the product (see request ## 1, 2, 3, and 6); a request for the Agency to initiate recalls of the product (see request #4); requests for the Agency to order changes to the formulation and labeling of the product, including requiring warnings (see requests ## 9, 10, 11, and 12); requests for the Agency to provide for public input on the petition

(see requests ## 7 and 8); a request for the Agency to order damages be paid by the company (see request # 14); requests for the Agency to initiate various types of enforcement action against the manufacturing firm and/or the product (see request ## 5, 15, and 16); and a request to investigate the thoroughness of the research conducted by the Veterinary Oral Health Council (VOHC) for the endorsement of the product (see # 13).

Since the time you filed your petition, the Greenies product line has been acquired by a different firm. The Greenies canine dental chews product was reformulated in September 2006, and the labeling was changed to reflect the new formulation. Consequently, many of the claims and requests for agency action in your petition do not apply to the currently marketed product. As such, FDA does not believe that it would be beneficial to the public health to use the agency's limited resources to investigate the safety of the old formulation. Insofar that your claims and requests apply to the current formulation, we address them in more detail under the relevant general categories.

The response to your specific claims and requests are addressed under the general categories below.

Category 1: Requests to investigate the safety of the product.

Your petition requests that FDA initiate a formal investigation of Greenies, conduct a survey of all veterinarians in the United States about their experiences with harm caused by Greenies, and create an active surveillance system to gather the incidence of Greenies-related injuries and deaths. The petition asserts that Greenies "can obstruct a dog's esophagus or intestines" and that "the obstruction creates secondary or subsequent health problems such as inflammatory bowel disease, ulcers, megaesophagitis, and esophagitis, and potentially death." (Petition, page 6)

The product, as formulated at the time of your petition, has not been manufactured for several years and is no longer marketed. FDA has compared the ingredients in the new and old formulations of the canine dental chews and notes that they are markedly different products. [2] According to the firm which acquired the Greenies product line, the formulation was changed to include ingredients selected for "high solubility and digestibility"; the reformulated dental chews were created in different sizes for dogs within respective weight ranges; and the product shape was changed to "encourage thorough chewing."[3]

Moreover, FDA has reviewed its complaint databases and found a substantial drop in complaints about Greenies products since the beginning of 2007, after the reformulated product went on the

[2] This review was completed by the Division of Animal Feeds, Center for Veterinary Medicine and involved a comparison of ingredients listed on a label of the product collected during a February 2006 inspection, and the list of ingredients on the firm's website in June, 2013.

[3] See http://vet.greenies.com/assets/pdf/en_US/dentalchew_soluble_digestable.pdf.

market.[4] During 2005 and 2006, the agency received 51 reports of choking, gastrointestinal (GI) obstruction, and GI non-obstruction associated with ingestion of Greenies dental chew type products in dogs. However, since 2007, the agency has received only 6 complaints regarding Greenies dental chew type products in dogs. Only two of these complaints involved GI obstructions, both of which were received in 2011. We believe that the difference in the number of safety reports shows a substantial decrease in complaints since the reformulated product was introduced.[5]

Because the formulation of Greenies has changed and the number of adverse events reported regarding Greenies has substantially decreased since you filed your petition, we do not believe an investigation into the safety of the currently marketed product is warranted and we deny your requests to initiate a formal investigation of Greenies, to conduct a survey of all veterinarians in the United States about their experiences with harms caused by Greenies, and to create an active surveillance system to gather the incidence of Greenie-related injuries and deaths. Your petition also requested that FDA initiate a formal investigation into and research of color additives included in Greenies. FDA denies this request. The label of the currently marketed product bears an ingredient list that includes sodium copper chlorophyllin. Although sodium copper chlorophyllin is approved for use to color citrus-based dry beverage mixes per 21 CFR § 73.125(c), it is not approved for use in animal food. FDA initiates investigations into the use of ingredients in animal food as resources and priorities permit. FDA's denial of your request is not a determination that the product is in compliance with the Federal Food, Drug, and Cosmetic Act, and should not be taken to mean that FDA has approved the use of the color additive in pet food products, such as Greenies.

Category 2: Request for the Agency to initiate recalls of the product.

Your petition included a request that the Agency ask the company to recall all Greenies or order such a recall pending completion of a formal investigation. However, because we have denied your requests to conduct an investigation of the safety of Greenies, we do not have a basis upon which we could grant your request that we ask the company to recall or order a recall "pending completion" of such survey and investigation. Furthermore, the formulation of the product changed in 2006, and the product that was the subject of your petition is no longer being manufactured and has not been marketed for several years. Therefore, even if FDA thought a recall was appropriate for the previously marketed product, we do not believe there is any product left to recall.

---

[4] We note that the Greenies product line marketed for dogs now includes Greenies Canine Dental Chews, Greenies Hip & Joint Care Dental Chews, and Greenies Pill Pockets. Our review of our safety database included a search for complaints about Greenies Dental Chew type products (Dental Chews and Hip & Joint Care) in dogs, which are most comparable to the product marketed prior to reformulation.

[5] The agency cautions that a report of injury or illness does not establish causation.

For these reasons, FDA is denying your request for FDA to ask "S&M to recall all Greenies or order such a recall pending completion of the survey and investigation requested in this petition."

Category 3: Requests for the Agency to order changes to the formulation and labeling of the product, including requiring warnings.

Your requests for the agency to order changes to the formulation and labeling are moot because, as explained above, Greenies canine dental chews has been reformulated to the extent that the product that is the subject of your petition is no longer being marketed. Furthermore, FDA has not determined that the current formula and manufacturing process for Greenies dental chews create a risk of harm to dogs from their ingestion. Moreover, FDA is not aware of and has no basis to believe that information or studies regarding adverse negative effects associated with Greenies are being withheld from the public. Therefore, putting aside other issues raised about the extent of FDA's authority to require your requested changes, FDA denies these requests.

Category 4: Requests for the Agency to provide for public input on the petition.

Your petition requests that FDA publish this citizen petition in the Federal Register and to hold a hearing or hearings at which interested parties can present evidence relevant to the claims in this petition. FDA denies your request.

In denying this request to publish the petition as a proposal in the Federal Register and to hold hearings, we considered whether such publication would assist us in responding to the particular requests in your petition. FDA regulations at 21 CFR § 10.30(h) authorize the Commissioner to use several procedures in reviewing a petition, including the publication of a Federal Register notice requesting information and views, or the holding of a hearing. These procedures are discretionary, and in this case we determined that publishing your petition as a proposal in the Federal Register and/or holding a hearing would not assist us in addressing the issues you presented in your petition. Because the product that is the subject of your petition is no longer marketed, FDA has decided not to expend its limited resources on an investigation of the product. As such, public commentary regarding the the product will not assist FDA in responding to the particular requests in your petition.

FDA notes that the public has the ability to submit comments and other input on a citizen petition through the Division of Dockets Management as part of FDA's citizen petition process. FDA regulations provide that a citizen petition that appears to meet certain specified requirements will be filed by the Division of Dockets Management, stamped with the date of filing, and assigned a docket number. 21 CFR § 10.30(c). Your petition was filed by the Division of Dockets Management on March 17, 2006, and assigned the Docket Number 2006P-0126/CP1. That Docket Number has since been renumbered as FDA-2006-P-0276. FDA regulations further provide that an interested person may submit written comments to the Division of Dockets Management on a filed petition, and that those comments will become part of the docket file. 21 CFR § 10.30(d).

FDA followed its normal procedures for accepting and filing your citizen petition, and has considered all comments in responding to your petition. This response, which is being sent to the Division of Dockets Management, will be placed in the docket and it, along with the petition, all supporting documents, and all comments received on the petition, are part of the administrative record of the decision with respect to this citizen petition.

Category 5: Request for the Agency to order damages be paid by the company.

Your petition requests that FDA "order payment of damages to owners of dogs determined to be harmed by Greenies, using some of the $340 million in revenues earned by S&M in 2005 from the sale of Greenies as the basis of a constructive trust for these payments." This request is denied. Ordering a firm to pay damages to private parties is outside the scope of FDA's authority.

Category 6: Requests for the Agency to initiate various types of enforcement action against the manufacturing firm and/or the product.

Your petition requests that FDA initiate a variety of enforcement actions against the manufacturer and the product. As explained above, the Greenies product line was acquired by another firm and has since been reformulated. Thus, the firm and product at issue in your petition no longer exist, and FDA denies your requests to take enforcement action against them.

First, we deny your request that FDA initiate a seizure of all Greenies from retailers and veterinarian offices if the product is not voluntarily recalled. Although the agency has authority under the Food, Drug, and Cosmetic Act to initiate enforcement action, including seizures of regulated products (see 21 U.S.C. § 334), such action is discretionary. Moreover, FDA could not exercise its discretion to initiate a seizure in this case because the agency has not made any compliance determinations that would justify seizure of the products. In addition, even if FDA had made a compliance determination, FDA is not aware of the existence of products manufactured from the old formulation and does not believe there is any relevant product available to seize.

Second, we deny your remaining requests for enforcement action.[6] You requested that FDA fine the firm to the maximum extent permitted under applicable regulations if it is found to have failed to disclose material facts associated with Greenies or violated any regulations or statutes under the jurisdiction of the Commissioner. You also requested that FDA pursue applicable remedies and procedures in accordance with 21 C.F.R. pt. 7, subpt. E." Because the product at issue in your petition is no longer being marketed, FDA has decided not to allocate its limited resources to conducting a compliance investigation.

[6] Because FDA is denying these requests, we do not need to reach the issue of whether any of these remedies would be available or appropriate under the FD&C Act.

Category 7: Request to investigate the thoroughness of the research conducted by the Veterinary Oral Health Council for the endorsement of the product.

This request raises a number of issues which would need to be thoroughly researched, including an investigation of which law or laws govern and which government agencies may share jurisdiction. Because the product that is the subject of your petition is no longer marketed and because the agency has not identified any safety concerns with the reformulated product, we decline to conduct an investigation of the research conducted by VOHC for its endorsement of Greenies dental chews. Again, we have decided that it would be in the public interest to focus our limited resources on addressing issues of current or greater public health concern. Therefore, we deny this request.

Conclusion:

For the reasons explained above, we are denying your petition under 21 CFR § 10.30.[7] Although we are denying the requests in your petition, we sincerely appreciate your interest in ensuring the safety of animal food products.

Sincerely,

Bernadette Dunham

Bernadette M. Dunham, D.V.M., Ph.D.
Director, Center for Veterinary Medicine

[7] We also want to take this opportunity to explain why you did not receive any documents in response to your request under the Freedom of Information Act. On October 15, 2008, FDA sent a letter to you inquiring whether you wanted us to continue processing your request, or whether you wanted to withdraw it. The letter stated, "If we do not receive a response from you by [November 15, 2008], we will assume that you no longer have a need for the requested records and that no further processing is necessary." Because you did not respond to this inquiry, we closed out your FOIA request.