March 17, 2006

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

## CITIZEN PETITION

The undersigned Petitioners submit this petition under 21 U.S.C. § 301, *et seq.*, of the Federal Food, Drug, and Cosmetic Act to request that the Commissioner of Food and Drugs take actions as described below. This petition complies with the requirements of 21 C.F.R. § 10.20, including without limitation that the representations herein are made to the best of the knowledge, information, and belief of the Petitioners and that the statements made in the petition are true and accurate.

## I. ACTIONS REQUESTED

Petitioners hereby request that the Commissioner take the following actions with regard to the animal product that is manufactured by S&M NuTec LLC ("S&M") and that is known as a "Greenie":

**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.

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

**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 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.

## II. STATEMENT OF GROUNDS

Following is a full statement, in a well organized format, of the factual and legal grounds on which the Petitioners rely, including all relevant information and views on which the Petitioners rely, as well as representative information known to the Petitioners which is unfavorable to the Petitioner's position.

### A. Facts Personally Known to Petitioners

In short, our Old English Sheepdog, Odin, is dead. To the best of our understanding, his death was the result of the accumulation of small chunks of Greenies material that lodged, unidentified, in his intestines, ultimately blocked his digestion, and in layman's terms ignited a firestorm of chronic inflammatory bowel disease which included ulcers in his stomach and esophagitis in his throat. Included in Attachment 1 to this petition are copies of pictures of Odin before the blockage and illnesses resulting from the Greenies. Attachment 2 contains copies of pictures of Odin after the blockage and illnesses resulting from the Greenies.

He was only four years old and 70 pounds when Petitioners gave him two or three Greenies within a one-month period of time because their veterinarian suggested Odin could use additional help in keeping his teeth clean. (He had annual hospital dental cleanings prior to this time.) The packaging indicated it would reduce plaque and tartar on his teeth and appeared to be an appropriate choice when suggested by a local pet food store employee. The packaging also had a special endorsement from the VOHC that Greenies would reduce plaque and tartar on his teeth. (Attachment 3 is a copy of the packaging from the bag of Greenies Petitioners bought.) Odin sat at the feet of Petitioners who watched him eat the Greenies, which were the size indicated for a large dog, and he chewed them into small pieces.

Several weeks after eating the third Greenie, on Thursday night, October 28, 2005, Odin started vomiting a bright yellow bile-colored substance. The next morning, Petitioners called their veterinarian who suggested that Petitioners watch him and call back if his condition worsened. On Saturday, October 29, 2005, his condition did worsen so Petitioners took him into their veterinarian hospital ("First Hospital"). Since this was not a dog who tended to eat foreign objects, Petitioners and the veterinarian did not feel there was anything unusual in his system. The veterinarian at the First Hospital thought he might have pancreatitis, some other intestinal condition, or perhaps a virus.

Petitioners took him home from the First Hospital, but his condition worsened, including more throwing up of bile, liquid excretions, lethargy, almost complete cessation of eating and drinking water, and grunting when he sat or laid down. Starting on Monday, October 31, 2005, Odin was hospitalized at the first of three veterinarian

hospitals. Initially, he was subjected to numerous tests and medications over the next two weeks while he was in and out of the First Hospital. Although it was clear that his intestines were tender and fluid filled, nothing was visible by either ultrasound or x-ray (and his vomiting prevented a barium study). During this period, his condition continued to deteriorate. On the morning of November 7, 2005, he started to shed his intestines in his stool, and Petitioners were sent by the First Hospital for emergency surgery to a second animal hospital ("Second Hospital").

Later that day on November 7, 2005, Petitioners took Odin to Second Hospital along with his records and x-rays. Odin had been brought into Second Hospital with symptoms that included vomiting, watery diarrhea, failure to eat, discomfort in his abdomen, and other problems. After his vomiting subsided sufficiently, Second Hospital did a barium series, found a blockage, and took him into surgery. During the surgery, they found "multiple small pieces of what appeared to be greenies – they were dark green and almost the constituency of clay." Petitioners were told that the small pieces of clay-like substance appeared to have coalesced into a tampon-shaped plug and swelled or expanded to cause complete blockage. The Surgery Report reflects that "[t]here was palpable foreign material within the ileum, cecum and ascending colon." Attachment 4 includes the Discharge Summary and Attachment 5 is the medical record from November 7, 2005, reflecting the fecal sample with his intestines.

Odin's weight dropped from 70 pounds before eating any Greenies to 45 pounds in the end. His stools were yellow liquid, and he was regurgitating water and small amounts of food on occasion when he ate. He had stopped eating and drinking water for the first five weeks and for the last two weeks. He was also diagnosed with two different opportunistic bacterial infections due to the immuno-suppressants he was taking, and he had massive fur loss (particularly troubling for a non-shedding dog) and skin irritations that were slow to heal and subject to infection as well. After four months and tens of thousands of dollars spent while unsuccessfully trying to get this disease under control through the work of dozens of veterinarians, Petitioners had to conclude there was no hope for his recovery so Petitioners relieved him of his pain and had him euthanized on March 1, 2006, at approximately 5:30 p.m., Pacific Time.

Instead of further detailing the facts during his illness until his death, Petitioners have attached to this petition as Attachment 6 a redacted version of the demand letter that Petitioners sent to S&M. This letter described in detail the facts of Petitioners' situation at that time, explained Petitioners' views on S&M's legal risks associated with its product and product labeling, requested compensation for the harm caused by its product, and requested the following actions by S&M:

1. Fix the notice on the Greenie product packaging to be more accurate. The product is not 100% edible and the notice must be made more conspicuous and indicative of the risks from lodging in the colon.

2. Re-formulate the product so that this problem cannot occur for other dogs.

3. Correct the S&M sales program to make the representations made by its sales people more accurate, i.e., that Greenies have been found to cause harm and death to some dogs. (This request was based on an incident experienced by one of Petitioners who had purchased special food for Odin during his hospitalization and had been talking with workers at a pet food store who indicated that salespeople for S&M had recently visited to do "damage control" and had told them there is no danger from eating Greenies. The retailer related to one of Petitioners that the S&M representative had assured them that all stories were "blown out of proportion" and that "the dog owners didn't use the product properly.")

Efforts to resolve Petitioners' dispute with S&M as described in the demand letter were unsuccessful and were ended by the Petitioners on March 1, 2006, the day Odin was put to sleep.

Petitioners attached a redacted version of the letter to this petition because Petitioners prefer not to include in a publicly available petition the names of the veterinarians who tried to save Petitioners' dog, and Petitioners' financial damages are irrelevant to this regulatory process. However, Petitioners will send the Commissioner the unredacted letter and the complete set of all of the attachments with the records from Petitioners' three veterinary hospitals, if requested pursuant to a formal investigation.

## B. Complaint Filed by Petitioners With the Agency and FOIA Request Submitted to the Agency

Petitioners contacted the Agency in order to file a complaint about the impact of Greenies on Odin. Camille Bennett Hoffman, the Consumer Complaint Coordinator in Seattle, Washington, spoke with one of the Petitioners on January 23, 2006, and indicated she would submit Petitioners' complaint to the Agency. Petitioners then filed a Freedom of Information Act ("FOIA") request to obtain a copy of their complaint and other relevant information on February 6, 2006. Attachment 7 is a copy of the FOIA Request.

Petitioners have not yet received the information requested in Attachment 7. On February 21, 2006, one of the Petitioners left a message with the Agency to confirm receipt of the FOIA request, and the Petitioner was told on February 22, 2006, by Brenda Dorsey, a staff person at the Agency, in a telephone conversation that the request had been received and information in response to the request was scheduled to be delivered

on March 16, 2006, if the Agency met the disclosure deadline required by law. However, she also indicated that requests are processed on a first-come, first-served basis and that it was not clear if the Agency would meet its disclosure deadline.

## C. Definition of the Problems With Greenies

The Greenies create two problems: One is that the product, even small amounts as in the case of Odin, can obstruct a dog's esophagus or intestines. As Petitioners' case indicates, such blockages are not always visible by routine tests such as those conducted by an ultrasound machine or by x-rays. The second problem is that the obstruction creates secondary or subsequent health problems such as inflammatory bowel disease, ulcers, megaesophagitis, and esophagitis, and potentially death. Both of these problems should be studied and solved under the auspices of the Agency because its mandate is to protect the public health, including the health of animals, and to "enhance public understanding, improve consumer protection, and assure uniform and consistent application of practices and procedures throughout the agency." 21 C.F.R. § 7.1

## D. Veterinarian Professional Journal Article Describing the Problem

Moments after Odin was euthanized, one of the Petitioners was discussing with the veterinarian the impact of the Greenies on Odin. The veterinarian gave the Petitioner a very recently published article entitled *Compressed Vegetable Chew Treats: A Common Gastrointestinal Foreign Body* by Elisa M. Mazzaferro, MS, DVM, PhD, Diplomate ACVECC, dated Feb. 2006, in the *NAVC Clinician's Brief.* A copy of the article is included as Attachment 8. In one of the pictures on the second page (4b), the large piece of a compressed vegetable chew treat appears to be a Greenie chunk.

In the Discussion, the author describes the Greenies disclaimer on its packaging and summarizes the inherent dangers with this product:

> Although the manufacturer states that owners should be present during chewing of the product to prevent gulping or rapid ingestion, realistically this is often not possible. Some manufacturers claim that the products are 100% digestible. However, digestion can take days, and before it can occur, large pieces can, and do, move past the pylorus and can cause life-threatening intestinal obstruction.

(Emphasis added.)

The description about how long digestion can take for these products and how it causes obstructions in the intestine mirror what happened to Odin and apparently have

happened to other dogs, as discussed below. Further, one of the "Take-Home Messages" from Dr. Mazzaferro is that "[e]ven with appropriate use, compressed vegetable chew treats can be ingested whole or bitten into pieces large enough to cause gastrointestinal obstruction."

Petitioners will search for other veterinarian research on this and related topics, and will supplement this petition with the results of this and other research, as well as local survey research they plan to conduct. In the meantime, the Commissioner cannot ignore the timeliness and importance of this article on this topic and the need to take direct and immediate action to address the Greenies problems just now being recognized and publicized by the veterinary community.

## E. Injuries and Death From Greenies Present an Underreported Public Health Problem

At the moment, only passive reporting of significant events occurs. S&M claims these are few in number. However, health professionals are well aware that data acquired through passive surveillance may not accurately reflect the magnitude of the risk for a specific population or the amount of disease that can be prevented. Therefore, to determine if passively reported cases of a negative event associated with Greenies are representative of the affected population, an active surveillance system would need to be set up. Otherwise, underreporting of the number of events will skew the projections on which health policy decisions are made.

An active surveillance system would need to cover all primary sources of medical care, i.e., veterinarians. It should also include secondary sources of reporting such as pet supply stores, pet catalog companies or kennel clubs and their memberships. Perhaps the most complete method of determining Greenie-related incidents would be to survey dog owners directly. This could be accomplished with a brief questionnaire being enclosed with annual state dog licensing renewal forms in a number of different areas of the country.

Petitioners' view on the underreporting of these problems for animals' health is based on its similarity to the situation the public faced in the early 1980s from HIV and AIDS related problems. During this time, Petitioner Dr. Roberta Kraus Wyde was studying at the UCLA School of Public Health for her PhD (having earned a Masters degree in Public Health there) with a concentration in epidemiology. One of the main problems in studying the transmission of HIV at that time was that it was unrecognized as a growing and/or unique problem in the general population. It was underreported and data was not shared such that the extent of the problem was readily identifiable. For several years in the mid-1980's, Petitioner Dr. Wyde coordinated a study for the Surgeon General to determine the efficacy of condom use in the prevention of the transmission of

HIV. She was part of a collaborative team that developed and administered surveys and worked with physicians, epidemiologists, community activists, and others to study the extent to which this disease had spread and to educate the public about identifiable risks just as AIDS was emerging as a major public health problem.

The Petitioner's experience with the underreporting of the spread of HIV has numerous parallels to the situation with injuries and deaths caused by Greenies. Consumption of Greenies is increasing dramatically, but so are injuries and deaths. Individuals are anecdotally reporting problems, but there is not any organized, professional analysis being conducted to verify the magnitude or cause of the problems. The Agency has jurisdiction over this problem with animal food, just as NIH, the CDC, or HHS has jurisdiction over how to investigate and cure diseases in the human population, and the Agency should take the initiative to analyze and fix any problems caused by this product.

On information and belief, the Petitioners understand that the Agency is conducting or will be conducting studies related to Greenies. Further, Petitioners understand from discussions that the veterinarian community is conducting additional studies to supplement the article published by Dr. Mazzaferro. However, notwithstanding such studies, the Agency should conduct comprehensive studies as described in this petition, particularly to address the underreporting problems with this product, and should initiate a proceeding in which interested parties could contribute valuable, practical information about the injuries and deaths caused by Greenies. Individual litigants are suing and more will sue S&M to be compensated for the harms and financial damages those individuals such as Petitioners have suffered. But the public needs a public forum such as only the Agency can provide to compile a comprehensive record.

## F. Public Reports of and Litigation From Deaths and Injuries From Greenies

In spite of the lack of empirical data, evidence is now clearly mounting around the United States that Odin is one of dozens, perhaps hundreds or thousands of dogs, which have been harmed from the effects of Greenies on their digestive systems. A couple whose dog died due to Greenies filed a lawsuit against S&M, as reflected in the complaint in Attachment 9, and a class action lawsuit has been filed in New York, as reflected in Attachment 10. In the class action lawsuit complaint, the plaintiffs allege events that were very similar to events affecting Petitioners' dog. Specifically, the Greenies became lodged in their dogs' intestines and swelled to a larger size while failing to break down, which caused damaging intestinal blockage.

In addition, Attachment 11 includes copies of articles about this product from newspapers and video investigations around the United States from such media outlets as

CNN, ABC Chicago, and KIRO-TV in Seattle, Washington. These news reports are just a few examples of the numerous investigative video reports beginning to surface due to the growing awareness of danger from this product.

## G. Representative Information Known to Petitioners Which Is Unfavorable to the Petitioners' Position

Following is a summary of information known to Petitioners which is unfavorable to the positions taken by Petitioners, and then Petitioners' response to such information.

### 1. Warning on Package.

The Greenies packaging provides a warning on the back of the packaging from the product Petitioners bought:

"Gulping any item can be harmful or even fatal to a dog."

This notice warned of dangers from gulping, but gulping did not occur in Odin's situation, as noted in Attachment 4. Instead, small chunks of whatever Greenies are made of accumulated in Odin's intestines.

The notice is also cursory and almost illegible, located on the third column in 4-pitch font, instead of being located in a conspicuous location with conspicuous font.

S&M conducted a press conference on February 22, 2006 to announce changes to its labeling to instruct consumers about how their dogs should eat Greenies. At that event, S&M stated that "Greenies are safe if they're fed and chewed by the dog as we have on the bag." (Page 5, Attachment 12.) This statement is not true: Odin chewed the Greenies and did not gulp them, and he is dead. The Agency should take action to stop these statements which mislead consumers into believing their dogs are safe from this product if the product is properly sized and chewed instead of being gulped.

### 2. Safety

S&M says Greenies are safe. The lawyer for S&M stated at its press conference that "we'd like to emphasize that Greenies are safe. . . ." (Page 28, Attachment 12)

However, at this same press conference, Mr. Roetheli (president and co-owner of S&M) states the product is "very safe relative to any of the options that I've seen anybody come up with and talk about, despite the fact that we have had a rare incident with it." (Page 33, Attachment 12) (Emphasis added). Thus, on one hand, the product is safe, but on the other hand it does cause injuries, however unfortunate for those rare incidents like Odin had.

S&M does not, in fact, know what the risks of injury or death are and is just guessing at the harms its product causes, as reflected in the following dialogue between and among S&M's president (Mr. Roetheli), its legal counsel (Mr. Brandt) and a reporter (L. Smitherman) at the press conference:

> J. Roetheli: No, either I or – somehow we got that number reversed. It's one incident per 8.1 million Greenies sold; and that's under a worst-case scenario.
>
> C. Brandt: Joe, if I can interrupt real quick, I think the number Joe is using, he's using a number that's been alleged in a lawsuit, which we think is highly exaggerated; we think it's a much larger number than it is.
>
> L. Smitherman: What do you mean? Is it one in 8.1 million, or not?
>
> C. Brandt: We believe it's substantially less than that. I mean that the odds are much greater than one in 8 million. The exact number, I don't think anybody knows exactly what that number may be –
>
> L. Smitherman: So what's the incident rate according to your information?
>
> C. Brandt: We believe it's substantially higher than that. I mean, I don't think we have an exact incident rate that we would have, say, one in whatever; but we believe it's much safer than one in 8 million.

(Pages 7-8, Attachment 12)

S&M does not indicate what its "worst case scenario" is, but this dialogue confirms S&M is ignorant about the real number because it has not fulfilled its duty to the public to assess the real statistical risks of harm. Thus, the Commissioner should order S&M to stop making untrue statements which mislead the public about the safety of the product and cause the public to purchase the product based on inaccuracies, and S&M should be required to conduct a real scientific study about the harms its product causes.

In the video clip from the CNN investigative report on Greenies, which was broadcast first on February 14, 2006, S&M's president and co-owner stated there was a very, very low risk from Greenies. From S&M's perspective, it appears that it knows the

extent of the risk of harm from its product and that the benefits outweigh whatever risk of harm it has assessed.

However, this statement is actually an admission that should raise serious concerns for the Commissioner. First, if S&M knows there is any risk of death or injury from this product, it should voluntarily correct the product to remove the risk or be required to do so by the responsible regulatory agency. Secondly, S&M does not indicate the extent of the risk, raising questions about the basis of his statement and implying it really does not know. Thirdly, if it does know, it should simply give the public this information on its packaging and let the Commissioner determine, using the expertise of the Agency, whether the risk is acceptable to the public. Also, if there was a study conducted in 2001 when the product was approved by the Agency, a new study is needed based on the huge numbers of dogs exposed to the hundreds of millions of Greenies sold since then.

**3.** Edibility

S&M states that the product is 100% edible. "Edible" is defined as "fit to be eaten" in *Merriam-Webster's Collegiate Dictionary, 11th ed.* Mr. Roetheli stated at the press conference that the packaging "says 100% edible, and that is true. I formulated it myself. It all begins as human food-grade ingredients." (Page 24, Attachment 12)

Yet, S&M's website indicates that the product contains ash. To the best of Petitioners' knowledge, ash is not a human food-grade ingredient. Based on these inconsistencies, the Commissioner should conduct an investigation into the real ingredients in Greenies and require non-edible components, such as ash, to be removed or noted more visibly on the packaging.

Further, how would the public and the Agency know the product is completely fit to be eaten? If S&M has statistical information about its product to indicate the product is 100% fit for eating with no level of risk from being consumed, S&M would have published it. This lack of disclosure implies it lacks real facts and is just guessing at the dangers from or safety of its product. Thus, the Commissioner should order disclosure of the basis of this statement or, more appropriately, conduct its own study with its own experts. Pending completion of such a study, the product should be recalled to reduce the risks to the public from the product.

**4.** Digestibility

S&M states that the product is 85% digestible. To S&M, digestible seems to mean it can be absorbed by a dog's body. Mr. Roetheli stated at S&M's press conference

that S&M has "conducted independent third-party tests on digestibility. It's what is known as an AAFCO protocol, which is the American Association of Feed Control Officials, that put out the specifications of how such a test should be done. We did that. What this independent lab found was that it was about 85% digestible, and that's a little bit higher than a premium dog food. It digests very well." (Page 21, Attachment 12)

However, S&M has not conducted appropriate scientific analysis to analyze the probability that the product ingredients in the remaining 15% can cause harm to dogs. The S&M website indicates that the product contains ash. Without appropriate scientific studies, Petitioners can only guess at what caused a mass of Greenie substance to lodge in Odin's intestines, but the description of the material from the surgeon sounds like it was a material similar to ash. If such a substance is part of the indigestible portion, the packaging shall reflect this fact, and the Agency should analyze what risks arise from the particular indigestible elements of Greenies.

The subsequent dialogue at the press conference addressed to what extent the size of a Greenie chunk and the extent to which it has been chewed might affect digestibility. According to Mr. Roetheli, the study "fed the dogs the product and then within the study, they would actually just take fecal samples and determine what type of nutritional value was absorbed by the dog and what actually passed through with this. . . . I might mention that all the feces and output is collected. Basically what they do is they measure everything that goes in and everything that comes out, and then that's basically how this AAFCO protocol determines digestibility. . . .What we know is basically the same as with many other foods. If you think about, for example, an apple, a potato, a carrot, even a piece of steak, if a dog gulps that whole piece, it will go down into the stomach and intestines, and there's too much volume of material there per surface area, and the dog tends to have a difficult time digesting it. In most cases what will happen is that the dog will pass it ultimately. On rare occasions, it will cause an obstruction and that can happen with anything." (Pages 22 – 24, Attachment 12) (emphasis added)

Petitioners understand that most of the product will pass through a dog. However, Mr. Roetheli again admits the product can and does cause obstructions. And, in Odin's case, the amounts were small and accumulated in his intestines. Was Odin the "rare" case or was he more typical than S&M wants to acknowledge? No one knows due to the lack of sufficient studies and the underreporting of problems by individuals, how prevalent this problem is. Therefore, the product should not be allowed to be sold until the scientific answer is clear.

The subsequent dialogue at the press conference on this issue (pages 25-26) addressed how long it takes for the product to break down in a dog's intestines:

> C. Brandt: As Joe was talking about earlier, I believe it depends upon the amount of surface area you have. If you have a very large piece, it's going to take a lot longer for the digestive juices to break it down.
>
> D. Fling: So if my dog swallows a chunk of a Greenie which is 85% digestible, but it's a really big chunk with limited surface area and it takes my dog two weeks – eventually his stomach acids will break it down, but in that two weeks, he becomes septic and dies – that seems to be the issue here, right?
>
> C. Brandt: It's going to depend on the dog. For some dogs it could take a day to digest a very large piece; for some it could be two days, for some, three. It's going to depend on the specific dog and what else is going on in their digestive systems.

Petitioners' dog, Odin, chewed the product and some of it never broke down but instead lodged in his intestines. The product stayed in his system for at least two weeks, not one or two days, and then caused an obstruction. Petitioners also wonder why a lawyer is opining on medical facts instead of S&M's professional veterinarian and on what facts legal counsel is basing his statements. Petitioners believe that there are no such facts and no data, and that S&M is just guessing while dogs die from eating the product.

**5.** Benefits from Greenies

S&M developed the Greenies product to help reduce plaque and tartar and to reduce tooth disease which can lead to death. Mr. Roetheli stated at the press conference that he would "really like to emphasize . . . that we keep this whole issue in balance, and that doing nothing is probably the worst thing that a dog owner can do in terms of periodontal disease, because it is a real killer." (Page 27, Attachment 12)

Unfortunately, Odin died before Petitioners had a chance to observe any improvement in Odin's teeth due to his consumption of Greenies. In Petitioners' opinion, Greenies can kill, so Petitioners feel there is not a balance being achieved by this product. They also believe that Mr. Roetheli should not make the decision about whether a product that he has created to reduce risks of death from tooth disease should be allowed to create other acknowledged risks of death.

There is also no question that the company will say many dogs love to eat this product. The company has stated that about 730 million have been sold. However, just because a product is palatable or beneficial for one part of a body does not mean it should be sold without removing its dangers to other parts.

The easiest positive example is morphine which can have enormous benefits, but has addictive characteristics and potentially dangerous side effects as well. The easiest negative example is tobacco, which millions of people love to use, but which also kills millions. In addition, just because a bag of Greenies is sold, it does not mean that it is consumed. If there is a problem that is noticed, an owner will simply stop feeding the Greenies to his or her pet.

Is this product any different conceptually from Vioxx? Initial studies had been conducted about possible negative impacts from the ostensibly beneficial drug. Yet, after sufficient data was collected from its practical usage and such data was analyzed and publicized, the FDA recalled the drug due to its negative impacts. This situation seems to parallel the Vioxx situation in practice, and the FDA should recall this product until it has fully studied the product and its negative risks.

**6.** Veterinarians Recommend the Product

Mr. Roetheli states that "the vast majority of vets are basically saying that they are safe; that dog owners need to do something for their dogs' dental, oral health. There's a lot of leading doctors out there that are advocating them, selling them, and are very supportive of what we're doing."

Mr. Brandt reiterates that "for a vast majority of the vets, they're not saying Greenies are not safe; they're just exercising caution, to make sure that their clients are receiving the best instructions possible."

Upon what studies are these statements based? According to the article published by Dr. Mazzaferro and Petitioners' experience with over a dozen veterinarians in Seattle who tried to save Odin, the vast majority recognizes the dangers from Greenies and recommends against its use. With increasing frequency, these veterinarians are having to surgically remove obstructions from compressed vegetable chews, particularly Greenies. S&M should be required to provide facts supporting these representations or be required by the FDA to stop making them.

The Veterinary Oral Health Council ("VOHC"), which is comprised of 10 veterinarians who are Board members, approved the use of Greenies due to their study of reduction in tartar and plaque. According to the VOHC Acceptance Study cited on the S&M website, 26 dogs were used in two studies which lasted over 42 days and which

showed that average plaque reduction was 14%, tartar reduction was 62% and gingivitis reduction was 33% when dogs received Greenies.

However, there is no indication on the VOHC website or S&M website that the VOHC studied any other effects of Greenies on dogs. This failure by the VOHC to consider other factors and to indicate on its seal that no other factors were considered misleads consumers who rely on seals like that of the VOHC in their product purchases. Petitioners relied on this seal which created implied warranties that were not adequately disclaimed on the Greenies packaging. Petitioners believe the VOHC and each of its Board members bear responsibility for harms caused by Greenies, and the FDA should require removal of their endorsement or inclusion of additional information on the Greenies packaging or take other appropriate action.

The Commissioner should also take regulatory notice of the significant changes added to the VOHC website since the recent press reports about Greenies and dangers from their ingestion. Attachment 13 includes the home page of the VOHC website on December 14, 2005, and Attachment 14 contains the web site home page on March 4, 2006. The web site home page dated March 4, 2006 includes an extensive disclaimer of responsibility and potential liability for harms caused by animal ingestion of "compressed animal treats" like Greenies. These changes implicitly reflect an acknowledgement of the dangers from Greenies and clearly indicate VOHC's desire to disclaim responsibility for the VOHC endorsement on the Greenies packaging.

## H. There Is No Incentive for S&M to Fix the Product

It is Petitioners' opinion that S&M will never fix the product to remove its dangers for several reasons. First, Mr. Roetheli is a zealous advocate for the position that better teeth will lead to fewer deaths of dogs and, as a result, the other risks from his product are acceptable, even if injury or death result. This type of zealotry may have some positive benefits, but Petitioners believe it blinds Dr. Roetheli to the need to protect the dog population from what he admits are inadvertent effects of an otherwise beneficial product. Many human-based products have the same problem, most recently Vioxx, but also Thalidomide, Bextra and Estrogen for HRT. Odin did not live long enough following his initial exposure to Greenies for Petitioners to know if Greenies would have helped the status of his dental health. However, if Petitioners had known there were such inadvertent dangers, Petitioners would never have bought the product as there were other methods for accomplishing cleaner teeth for Odin that did not have a risk of harm in the past.

Which raises the second reason why S&M won't ever fix the problem unless forced to do so: money. Mr. Roetheli admits that in 2005 alone the company earned $340 million in revenue. After starting only eight years ago and growing at a breath-

taking and apparently exponential rate, S&M is now a huge money making machine. For S&M to change a product that will earn $1 billion a year shortly, it would be bad business and could jeopardize his huge and growing personal wealth since he and his family apparently own all of the company.

Thirdly, recalling or changing its product would operate as an admission that the product harmed the dogs of the people who have sued S&M and will sue it in the future for their damages. Why help its antagonists by acknowledging the product needs to be changed or could even be changed into a new and improved version? Petitioners doubt that S&M would take that risk.

Fourthly, S&M claims it will change its packaging to give more information to the public, but the notice cannot be accurate until a comprehensive, scientifically based study is conducted by the FDA or under its jurisdiction to assess the risks from this product. Petitioners believe that S&M is simply changing its labeling to reduce risks from violating the Uniform Commercial Code ("UCC") requirements that disclaimers of warranties and remedies be conspicuous in order to be enforceable. As noted in Attachment 6, Petitioners apprised S&M that they believe the notice is unenforceable under the UCC, thereby exposing S&M to unlimited direct, consequential and incidental damages caused by Greenies. The type of notice that is needed would explain the inherent health risks and make conspicuous the information needed by purchasers of this good to make an informed decision, which is not likely without the Commissioner's direct requirement.

Petitioners speculate that the final reason the product will not be changed may be because S&M may have filed to register a patent or patents on the product and changing the product might remove its patentability. Petitioners' guess is based on the desire of the company to dominate the market for this product, as shown by its litigation against T.F.H. Publications, Inc. to protect its trademarks and its statements about creating a new market. (Page 3, Attachment 12). Also, the General Counsel of S&M is a patent attorney. Until the patent or patents are granted, the public will not know whether this guess is correct. However, if it is correct, S&M would be hard pressed to announce changes to a product so that it would have to change its possible patent that could grant it a monopoly over this market.

## III. LEGAL BASIS FOR PETITION AND REQUESTED AGENCY ACTIONS

### A. Failure to Reveal Material Facts

On information and belief, the S&M packaging is misleading and fails to reveal facts in violation of both subsections (a)(1) and (a)(2) of 21 C.F.R. § 1.21 which state that:

> (a) Labeling of a food, drug, device, or cosmetic shall be deemed to be misleading if it fails to reveal facts that are:
>
> (1) Material in light of other representations made or suggested by statement, word, design, device or any combination thereof; or
>
> (2) Material with respect to consequences which may result from use of the article under: (i) The conditions prescribed in such labeling or (ii) such conditions of use as are customary or usual.

The labeling states that the product is 100% edible, i.e., fit to be eaten. Yet, as indicated above, evidence has arisen by the gastrointestinal illness, blockage and death of numerous dogs, including Odin, that the product is not 100% fit to be eaten.

The labeling also states that gulping of the product may be fatal. However, even if chewed, the product can be fatal as in the case of Odin.

Thus, the Agency should exercise its authority to require changes in the labeling of this dangerous product. In addition, the Agency should grant the Petitioners' requested actions described above, including but not limited to either seizing the products or requiring their recall, and initiating immediate research to determine to what extent the product is actually edible, digestible and safe or unsafe before more dogs die from ingesting it.

## B. Imminent Hazard to the Public Health

On information and belief, the S&M product creates an imminent hazard to the public health in violation of 21 C.F.R. § 2.5 because it poses a "significant threat of danger to health . . . [and] creates a public health situation (1) that should be corrected immediately to prevent injury, and (2) that should not be permitted to continue while a hearing or other formal proceeding is being held." Dogs are dying and being injured while the Agency considers this petition. Even S&M admits that there is a risk of death from its product, although it does not know if it is 1 in 8 million Greenies or 1 in 8 Greenies according to Attachment 12. Due to the underreporting problem and the company's own ignorance about these risks and due to the growing evidence of such injuries or death, there is an imminent hazard to the public health and the Agency should grant the Petitioners' requested actions described above.

**C. Methods of Analysis**

On information and belief, S&M violations of other regulations require that the Agency initiate its own investigation and analysis under 21 C.F.R. § 2.19 to assess the effects of Greenies on animals. Such an investigation would not vitiate the need for S&M to conduct its own studies to "demonstrate that [it] can perform the method properly through the use of positive and negative controls and recovery and reproducibility studies."

**D. Recalls**

On information and belief, S&M is in violation of several Agency regulations, and the Commissioner should order S&M to recall its product in accordance with 21 C.F.R. pt. 7, subpt. C. If S&M won't recall the product, the Commissioner should initiate legal action, e.g., seizure, as permitted by 21 C.F.R. § 7.3(g). The Agency would be justified in taking actions requested by Petitioners, including requiring that S&M remove or correct its product if it is in violation of FDA regulations because Greenies pose a Class I health hazard:

> (1) Class I is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.

A recall would be one, but not the only, appropriate step in this Greenie situation. Section 7.40(a) indicates that a recall "takes place because manufacturers and distributors carry out their responsibility to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective." S&M admits its products create a risk of injury, as yet unclear how great, and should voluntarily recall its products. Since it would be impossible to correct the products that are resident in retailers and veterinarian offices, S&M should be required to remove them. Going forward, it should also correct the cause of the problems the product creates. This regulation is clear on this requirement due to the risk of injury admitted by S&M.

The Agency should also empower an ad hoc committee of FDA scientists to conduct its own evaluation of the health hazard presented by a product while considering the recall of this product. Guidance is given in the regulation about the scope of inquiry of such a committee, including:

> (1) Whether any disease or injuries have already occurred from the use of the product.

(2) Whether any existing conditions could contribute to a clinical situation that could expose humans or animals to a health hazard. Any conclusion shall be supported as completely as possible by scientific documentation and/or statements that the conclusion is the opinion of the individual(s) making the health hazard determination.

(3) Assessment of hazard to various segments of the population, e.g., children, surgical patients, pets, livestock, etc., who are expected to be exposed to the product being considered, with particular attention paid to the hazard to those individuals who may be at greatest risk.

(4) Assessment of the degree of seriousness of the health hazard to which the populations at risk would be exposed.

(5) Assessment of the likelihood of occurrence of the hazard.

(6) Assessment of the consequences (immediate or long-range) of occurrence of the hazard.

The Agency should develop the recall strategy required by 21 C.F.R. § 7.42 to address the factors included in the regulation, including:

(i) Results of health hazard evaluation.
(ii) Ease in identifying the product.
(iii) Degree to which the product's deficiency is obvious to the consumer or user.
(iv) Degree to which the product remains unused in the market place.
(v) Continued availability of essential products.

The strategy should include a public warning in accordance with 21 C.F.R. § 7.42(b)(2) to alert the public that a product being recalled presents a serious hazard to the health of animals. Such a warning could be included as a:

(i) General public warning through the general news media, either national or local as appropriate, or

(ii) Public warning through specialized news media, e.g., professional or trade press, or to specific segments of the population such as physicians, hospitals, etc.

If S&M refuses to pursue a recall of its product, the Agency should order such a recall pursuant to 21 C.F.R. § 7.45(a). The Agency already knows that the product "presents a risk of . . . injury" and "agency action is necessary to protect the public health and welfare."

## E. Initiation of Administrative Proceedings

The Agency has the authority under 21 C.F.R. § 10.25 to initiate several types of administrative proceedings. Petitioners are interested parties petitioning the Agency pursuant to 21 C.F.R. § 10.25(a)(2) to take action. The Commissioner can also take other forms of administrative action, as described in 21 C.F.R. §§ 10.25(b) and (c). The public has a right to know more about this product that the manufacturer admits poses a health risk to animals but has not adequately studied that risk.

Publishing this petition in the Federal Register would allow interested parties to respond with comments about their knowledge and experience. The Commissioner could also initiate hearings as permitted under Parts 13, 14, 15, and 16. As a result, Petitioners request that the Commissioner take the actions requested above pursuant to this regulation for appropriate public participation in this process to protect the health of dogs in the United States.

## F. Color Additives

On information and belief, the Greenies product contains color additives subject to 21 C.F.R. pt. 70. The product label indicates that it contains chlorophyll which gives the product its green color and perhaps has purposes other than coloration. Therefore, the product appears to contain a color additive as defined in 21 C.F.R. § 70.3. As a result, the product is subject to specific safety regulations and procedures, including restrictions, packaging and labeling (Subpart B), petitioning (70.19), and safety evaluations (Subpart C). If S&M has filed such a petition and conducted such safety evaluations, the results of the evaluation should be disclosed to the public or at least in response to Petitioners' FOIA request. If not, the Agency should take necessary and appropriate actions to apply its regulations.

## G. Animal Food Labeling

On information and belief, S&M is in violation of 21 C.F.R. Part 501 in its animal food labeling. The labeling is not clear and conspicuous as required by this Part and is misleading and confusing, particularly with regard to what extent the product is edible, digestible or dissolvable and what these terms mean to a consumer. It also lacks all substances, such as ash, on the labeling.

## H. Criminal Violations

Out of an abundance of caution and to give the manufacturer the benefit of the doubt, the Commissioner should conduct necessary studies, investigations, analysis and hearings in order to determine to what extent animals are in danger from Greenies. Until such analyses are conducted, there is no way of knowing whether there has been a violation of the Federal Food, Drug and Cosmetic Act or another Federal Statute and, as described in 21 C.F.R. § 7.84, the Commissioner is obligated to take appropriate action. However, if the Agency finds that criminal violations may have occurred, the Agency is obligated to pursue applicable remedies under 21 C.F.R. pt. 7, subpt. E.

## CERTIFICATION

The undersigned certify, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the Petitioners which are unfavorable to the petition.

Richard S. Wyde

Richard S. Wyde, Esq.

Roberta Kraus Wyde

Roberta Kraus Wyde, MPH, PhD

4048 East Mercer Way
Mercer Island, WA 98040
(206) 236-5161 (Home)
(206) 628-7796 (Richard S. Wyde Office Direct Line)

## IV. ATTACHMENTS

Attachment 1: Copies of Pictures of Odin Before the Blockage and Illnesses Resulting from the Greenies

Attachment 2: Copies of Pictures of Odin After the Blockage and Illnesses Resulting from the Greenies

Attachment 3: Packaging from Bag of Greenies

Attachment 4: Odin's Discharge Summary from Second Hospital

Attachment 5: Odin's Medical Record from November 7, 2005, Reflecting the Fecal Sample with His Intestines

Attachment 6: A Redacted Version of the Demand Letter Petitioners Sent to S&M

Attachment 7: Petitioners' FOIA Request to the FDA

Attachment 8: *Compressed Vegetable Chew Treats: A Common Gastrointestinal Foreign Body* by Elisa M. Mazzaferro, MS, DVM, PhD, Diplomate ACVECC, dated February 2006 in the *NAVC Clinician's Brief*

Attachment 9: Michael Eastwood and Jennifer Reiff Complaint against S&M NuTec LLC

Attachment 10: Class Action Complaint

Attachment 11: Articles about Dangers from Greenies

Attachment 12: Transcript from S&M Press Conference, February 22, 2006

Attachment 13: Veterinary Oral Health Council Web Site Pages, December 14, 2005

Attachment 14: Veterinary Oral Health Council Web Site Pages, March 4, 2006

March 20, 2006

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

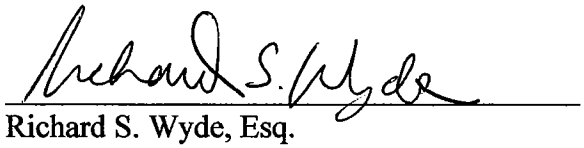
**CITIZEN PETITION**
**SUPPLEMENT NO. 1**

The undersigned Petitioners submit this Supplement No. 1 to their petition that was filed on March 17, 2006 under 21 U.S.C. § 301, *et seq.*, of the Federal Food, Drug, and Cosmetic Act to request that the Commissioner of Food and Drugs take actions as described in such petition. This Supplement No. 1 to their petition complies with the requirements of 21 C.F.R. § 10.20, including without limitation that the representations herein are made to the best of the knowledge, information, and belief of the Petitioners and that the statements made in the petition are true and accurate.

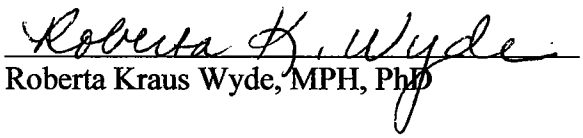
In this Supplement No. 1, Petitioners submit their claim for categorical exclusion under 21 C.F.R. §§ 25.30, 25.31, 25.32, 25.33, or Sec. 25.34 or an environmental assessment under 21 C.F.R. § 25.40.

**CERTIFICATION**

The undersigned certify, that, to the best knowledge and belief of the undersigned, Petitioners' petition and this Supplement No. 1 to Petitioners' petition include all information and views on which the Supplement No. 1 to the petition relies, and that the petition includes representative data and information known to the Petitioners which are unfavorable to the petition.



Richard S. Wyde, Esq.



Roberta Kraus Wyde, MPH, PhD

4048 East Mercer Way
Mercer Island, WA 98040
(206) 236-5161 (Home)
(206) 628-7796 (Richard S. Wyde Office Direct Line)

March 20, 2006

4256 6 MAR 20 A12:56

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**CITIZEN PETITION**
**SUPPLEMENT NO. 1**

The undersigned Petitioners submit this Supplement No. 1 to their petition that was filed on March 17, 2006 under 21 U.S.C. § 301, *et seq.*, of the Federal Food, Drug, and Cosmetic Act to request that the Commissioner of Food and Drugs take actions as described in such petition. This Supplement No. 1 to their petition complies with the requirements of 21 C.F.R. § 10.20, including without limitation that the representations herein are made to the best of the knowledge, information, and belief of the Petitioners and that the statements made in the petition are true and accurate.

In this Supplement No. 1, Petitioners submit their claim for categorical exclusion under 21 C.F.R. §§ 25.30, 25.31, 25.32, 25.33, or Sec. 25.34 or an environmental assessment under 21 C.F.R. § 25.40.

**CERTIFICATION**

The undersigned certify, that, to the best knowledge and belief of the undersigned, Petitioners' petition and this Supplement No. 1 to Petitioners' petition include all information and views on which the Supplement No. 1 to the petition relies, and that the petition includes representative data and information known to the Petitioners which are unfavorable to the petition.

Richard S. Wyde

Richard S. Wyde, Esq.

Roberta K. Wyde

Roberta Kraus Wyde, MPH, PhD

4048 East Mercer Way
Mercer Island, WA 98040
(206) 236-5161 (Home)
(206) 628-7796 (Richard S. Wyde Office Direct Line)