

*Pet Food Institute Public Comments on CVM GFI #284 Using Relative Supersaturation to Support
“Urinary Tract Health” Claims for Adult Maintenance Cat Food*

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The Pet Food Institute (PFI) appreciates the opportunity to provide comments regarding the agency’s November 30, 2023, request for public input on the draft guidance for industry concerning Relative Supersaturation To Support “Urinary Tract Health” Claims for Adult Maintenance Cat Food.

Established in 1958, PFI is the trade association and the voice of U.S. cat and dog food manufacturers. Our members account for the vast majority of the pet food and treats made in the United States, with more than \$60 billion in domestic annual dog and cat food and treats sales and annual exports of more than \$2.3 billion. PFI membership also includes companies that supply ingredients, equipment, and services to dog and cat food makers. We are all proud to be feeding over 186 million dogs and cats in U.S. households.

PFI appreciates the agency’s willingness to engage with industry stakeholders on this important topic and for proposing to standardize a pathway for how manufacturers can support urinary health claims for certain adult maintenance cat foods. We value the opportunity to provide industry feedback on this important consideration.

There are some areas that we feel should be considered before the final guidance is published. These are listed below.

First, we feel it is important for the term Relative Supersaturation to be clearly defined in any final guidance. Please consider adding “relative supersaturation (RSS) is the molar concentration of solutes, often comprised of minerals and organic compounds, relative to their concentration in water” to the background section of the Guidance for Industry #284.

Second, there are several different software and method programs available to demonstrate the efficacy of altering the urolith formation in the animal. Companies should be held to the same standard to prove validation regardless of the software or method used. Since different programs may deliver different results, it would be helpful to know FDA expectations for how the programs or algorithms will be validated.

Third, the draft guidance includes details related to supporting studies. The final Guidance for Industry needs clear guidelines for studies, including:

- The inclusion of blood parameters and at a minimum, health indicators such as stool quality and body weight. Differences in regulatory interpretations can result in confusion and misguidance. It has been proven that dietary water intake significantly impacts the RSS value of urine, therefore hydration status needs to be considered as a confounding factor.
(Buckley CM, Hawthorne A, Colyer A, Stevenson AE. Effect of dietary water intake on urinary output, specific gravity and relative supersaturation for calcium oxalate and struvite in the cat. Br J Nutr. 2011 Oct;106 Suppl 1:S128-30. doi: 10.1017/S0007114511001875. PMID: 22005408.)
- It is important that CVM provides clear study design requirements. How was the 40-day utility study determined? With 4 data collections, this could result in keeping animals on a trial with 26 weeks of blood and urine collection, possibly resulting in questions of animal welfare and responsible use of resources. Research, including the supporting references, does not seem to support the need for a study of that duration. Published literature has shown successful studies within 10 to 14 days.
- FDA is establishing an extensive protocol in this draft guidance document, more so than what exists in the protocol guidelines for products bearing “Reduces Urinary pH” claims (GFI #55). Therefore, if manufacturers follow the protocol guidelines, there should not be a need to continue the study for up to an additional six months.

Fourth, in section 4 “Other Considerations” of the draft, FDA requires that appropriate statistical comparisons be made to detect possible differences in safety parameters. It is important that CVM clarify what it means by “safety parameters.”

Fifth, PFI asks for clarification on the reason(s) the draft guidance has reduced the acceptable limits to the midpoint of the metastable supersaturation range. If RSS values of <2.5 (struvite) and <12 (CaOx) have been shown to be efficacious, then why is CVM suggesting to cut that in half (≤ 1.8 , ≤ 6.0 respectively)?

Sixth, the draft guidance requests “A complete quantitative formulation of the product.” It is important that CVM accept these ingredient inclusion levels as ranges to maintain the proprietary nature of formulas. Ranges are currently accepted for other CVM reviewed product

claim documentation, such as for products promoted with Hairball Control and Reduced Urinary pH claims.

Finally, the recommended mechanism of action statement in the draft guidance is not consumer-friendly and unlikely to fit on smaller packages, like 3 oz cans. Pet food manufacturers request more flexibility on the use of statements such as, “supports urinary health.”

On behalf of PFI members, whose nearly 30,000 employees in 33 states provide safe food for the 186 million pets across the United States, we appreciate the opportunity to share our views and look forward to issuance of a final guidance that will allow for the safe use of relative supersaturation data in urinary health claims in food for cats.

Sincerely,



Dana Brooks
President and CEO Pet Food Institute