



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2023-D-4095]

### Using Relative Supersaturation to Support “Urinary Tract Health” Claims for Adult Maintenance Cat Food; Draft Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft guidance for industry #284 entitled “Using Relative Supersaturation to Support “Urinary Tract Health” Claims for Adult Maintenance Cat Food.” FDA’s Center for Veterinary Medicine (CVM) has evaluated the use of relative supersaturation (RSS) methodology to support urinary tract health claims for certain adult maintenance cat food. RSS is a measurement that estimates the potential for crystal formation and bladder stone growth, which is a common affliction in cats. This draft guidance provides recommendations for how pet food manufacturers can use RSS methodology to substantiate general structure or function claims that an adult maintenance cat food supports urinary tract health by promoting a healthy mineral content in the urinary tract.

**DATES:** Submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2023-D-4095 for "Using Relative Supersaturation to Support "Urinary Tract Health" Claims for Adult Maintenance Cat Food." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at

the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish

Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Karen Donnelly, Center for Veterinary Medicine (HFV-227), Food and Drug Administration, 12225 Wilkins Avenue, Rockville, MD 20852, 240-402-9802, karen.donnelly2@fda.hhs.gov.

**SUPPLEMENTARY INFORMATION:**

I. Background

FDA is announcing the availability of a draft guidance for industry #284 entitled “Using Relative Supersaturation to Support “Urinary Tract Health” Claims for Adult Maintenance Cat Food.” RSS methodology is a measurement that estimates the potential for crystal formation and bladder stone (urolith) growth, which is a common affliction in cats. One of the primary conditions for urolith formation in any species is oversaturation of the urine with dissolved substances (solutes) that have the potential to precipitate out of solution and form crystals. These crystals can eventually grow into uroliths. The two most common types of uroliths in cats are magnesium ammonium phosphate (struvite) and calcium oxalate (CaOx).

Based on concerns about uroliths, pet food manufacturers use various formulation strategies to make adult maintenance cat food, with general structure or function claims, that support urinary tract health (UTH cat food). Historically, manufacturers of UTH cat food restricted the magnesium content and/or formulated their cat food to produce slightly acidic urine (pH of 5.9 to 6.4). The slight acidity and low magnesium content create a urinary environment that is unfavorable for struvite crystallization and urolith growth but may be favorable for CaOx urolith growth in predisposed cats. Formulating cat food based on RSS methodology is a more recent dietary strategy that some pet food manufacturers use to create UTH cat food. RSS provides a numerical measurement of the degree of saturation of a specific urolith-forming substance, and thus a quantitative method to evaluate the risk of urolith formation. The

principles of RSS apply to all urolith types, so UTH cat food based on RSS methodology has the potential to help protect cats from both struvite and CaOx uroliths.

In response to requests from pet food manufacturers, CVM has evaluated the use of RSS methodology to support urinary tract health claims for certain adult maintenance cat food. This draft guidance provides recommendations for how a cat food manufacturer can use RSS methodology to substantiate general structure or function claims that an adult maintenance cat food supports urinary tract health by promoting a healthy mineral content in the urinary tract. This draft guidance also includes information we recommend the manufacturer submits to us to ensure the urinary tract health claim is substantiated.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Using Relative Supersaturation to Support "Urinary Tract Health" Claims for Adult Maintenance Cat Food." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## II. Paperwork Reduction Act of 1995

FDA tentatively concludes that this draft guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

## III. Electronic Access

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: November 27, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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