White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Temporary Marketing Permit Applications—21 CFR 130.17(c) and (i)

OMB Control Number 0910–0133—Extension

This information collection request supports FDA regulations found in 21 CFR 130.17 (section 130.17). Section 401 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 341) directs FDA to issue regulations establishing definitions and standards of identity (SOIs) for food. Under section 403(g) of the FD&C Act (21 U.S.C. 343(g)), a food that is subject to a definition and SOI prescribed by regulation is misbranded if it does not conform to such definition and SOI. Section 130.17 provides for the issuance by FDA of temporary marketing permits (TMPs) that enable the food industry to test consumer acceptance and measure the technological and commercial feasibility in interstate commerce of experimental packs of food that deviate from applicable definitions and SOIs. Section 130.17(c) enables the Agency to monitor the manufacture, labeling, and distribution of experimental packs of food that deviate from applicable definitions and SOIs. The information so obtained can be used in support of a petition to establish or amend the applicable definition or SOI to provide for the variations. Section 130.17(i) specifies the information that a firm must submit to FDA to obtain an extension of a TMP. To assist respondents with the TMP process, we have developed guidance entitled ''Temporary Permits for Interstate Shipment of Experimental Packs of Food Varying from the Requirements of Definitions and Standards of Identity: Guidance for Industry'' (November 2021). This resource can be found on our website *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-temporary-permits-interstate-shipment-experimental-packs-food-varying-requirements.*

Description of Respondents: Respondents to this collection of information include private sector businesses including institutional and/or industrial customers and food industry members such as manufacturers, packers, or distributors desiring to apply for a TMP or TMP extension.

In the **Federal Register** of July 17, 2023 (88 FR 45431), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
130.17(c); Request for TMP	13	2	26	25	650
130.17(i); Request for TMP extension	1	2	2	2	4
Total					654

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: November 24, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–26300 Filed 11–29–23; 8:45 am]

BILLING CODE 4164–01–P

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 February 28, 2024 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.

[FR Doc. 2023–26306 Filed 11–29–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2459]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Product Jurisdiction and Combination Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by January 2, 2024.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0523. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Product Jurisdiction and Combination Products—21 CFR Parts 3 and 4

OMB Control Number 0910–0523—Extension

This information collection helps support implementation of statutory requirements that govern product jurisdiction and combination products. Congress expressly directed FDA to assign combination products to the appropriate Agency component for regulation as set forth in section 503(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353(g)). Congress also expressly directed FDA to determine the classification of a product as a drug, biological product, device, or combination product, or the component of the Agency that will regulate the product, as applicable, in response to a request submitted under section 563 of the FD&C Act (21 U.S.C. 360bbb–2).

Regulations in 21 CFR part 3 provide for product classification determinations and FDA designation on which Agency component will have primary jurisdiction for any drug, device, biological, or combination product, where such jurisdiction is unclear or in dispute. These determinations are made by our Office of Combination Products (OCP) upon receiving Requests for Designation (RFDs). We maintain a web page that includes contact and resource information pertaining to the RFDs process at *https://www.fda.gov/combination-products/jurisdictional-information.* As communicated on our web page, FDA welcomes comments from interested stakeholders on issues pertaining to OCP and encourages medical product developers to contact us if they are uncertain about the classification or assignment of their products and with questions regarding premarket or postmarket considerations for combination products. A dedicated mailbox is established at *combination@fda.hhs.gov.*

Similar to the RFD process, we have established the Pre-RFD process for sponsors to obtain preliminary, nonbinding feedback regarding medical product classification and assignment. Although Forms FDA 5003, 5004, and 5005 (pre-request and request for designation forms) were previously developed to facilitate information collection for Pre-RFDs and RFDs, we have more recently issued the following Agency guidance documents to provide instruction and recommendations to respondents regarding the submission of RFDs and Pre-RFDs.

- The guidance document entitled, ''How to Write a Request for Designation'' (April 2011), provides instruction regarding the information that needs to be submitted to OCP in an RFD as described in 21 CFR 3.7. The guidance is available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/how-write-request-designation-rfd.*
- The guidance document entitled ''How to Prepare a Pre-Request for Designation,'' (February 2018) was developed to assist sponsors in obtaining a preliminary, non-binding assessment regarding the classification and assignment of products from OCP through the Pre-RFD process. The guidance explains the Pre-RFD process and helps a sponsor understand the type of information to provide in a Pre-RFD submission. The guidance is available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/how-prepare-pre-request-designation-pre-rfd.*
- This information collection also includes burden associated with Combination Product Agreement Meetings (CPAM) requests. The guidance document entitled, ''Requesting FDA Feedback on Combination Products,'' (December 2020) was developed to discuss ways in which combination product sponsors can obtain feedback from FDA on scientific and regulatory questions and to describe best practices for FDA and sponsors when interacting on these topics. The guidance is available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requesting-fda-feedback-combination-products.*

The guidance documents were issued consistent with our good guidance practice regulations in 21 CFR 10.115, which provide for public comment at any time.

The information collection also includes regulations in 21 CFR part 4 that govern current good manufacturing practice requirements and postmarketing safety requirements for combination products. We expect, however, that burden attendant to the associated recordkeeping, reporting, and/or disclosure activities is already accounted for in approved information collections that apply to drug, device, and/or biologic products specifically and respectively. Therefore, we do not ascribe separate burden in this information collection request for the activities generated by these requirements.

Respondents to the information collection are sponsors of medical products, including combination products. Based on submissions received by OCP during fiscal years 2020, 2021, and 2022, we account for 135 respondents annually.

In the **Federal Register** of July 31, 2023 (88 FR 49467), we published a 60-day notice soliciting comment on the proposed collection of information. One comment was received expressing interest in combination product