Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biologic product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, Nuzyra Injection (NDA 209817) (omadacycline). Nuzyra Injection (NDA 209817) is indicated for the treatment of adult patients with the following infections caused by susceptible microorganisms:

- Community-acquired bacterial pneumonia, and
- Acute bacterial skin and skin structure infections.

Subsequent to this approval, the USPTO received a patent term restoration application for Nuzyra Injection (NDA 209817) (U.S. Patent No. 7,553,828) from Paratek Pharmaceuticals, Inc., and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated December 23, 2019, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of Nuzyra Injection (NDA 209817) and Nuzyra Tablets (NDA 209816) represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the products' regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for Nuzyra Injection (NDA 209817) is 4,361 days. Of this time, 4,118 days occurred during the testing phase of the regulatory review period, while 243 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* October 26, 2006. The applicant claims September 26, 2006, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was October 26, 2006, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* February 2, 2018. FDA has verified the applicant's claim that the NDA for Nuzyra Injection (NDA 209817) was initially submitted on February 2, 2018.

3. *The date the application was approved:* October 2, 2018. FDA has verified the applicant's claim that NDA 209817 was approved on October 2, 2018.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,812 days of patent term extension.

Note: We have determined that the regulatory review period for the human drug product, NUZYRA, approved under NDA 209817 is the same as the regulatory review period determined for the human drug product, NUZYRA, approved under NDA 209816.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: November 27, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–26363 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–2562]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Temporary Marketing Permit Applications

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 0910–0133. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three

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