products for compliance with the requirements of section 403(w)(1) of the FD&C Act, along with the time needed to make any needed modifications to the labels of those products. We believe firms have already redesigned their labels to comply with requirements under the Food Allergen Labeling and Consumer Protection Act of 2004. However, this estimate accounts for firms that will redesign their label to comply with requirements under the FASTER Act. Our estimated reporting burden is based on our past experience with these submissions. We have increased our cumulative estimate by 12,552 hours and 776 responses annually to reflect the inclusion of sesame as a major food allergen.

Dated: December 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–27018 Filed 12–7–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2851]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Time and Extent Applications for Nonprescription Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) 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 8, 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 0910–0688. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *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.

Time and Extent Applications for Nonprescription Drug Products

OMB Control Number 0910–0688—Revision

I. Background

This information collection supports certain Agency regulations in part 330 (21 CFR part 330) regarding over-the-counter (OTC) human drugs and associated guidance. Specifically, FDA regulations in §§ 330.14 and 330.15 (21 CFR 330.14 and 330.15) establish additional criteria and procedures for classifying OTC drugs as generally recognized as safe and effective and not misbranded. These regulations provide that OTC drug products introduced into the U.S. market after the OTC drug review began in 1972 and OTC drug products without any marketing experience in the United States can be evaluated under the OTC monograph system if the conditions (*e.g.,* active ingredients) meet certain ''time and extent'' criteria outlined in the regulations. The regulations in § 330.14 allow a sponsor to submit certain information to the Agency in a time and extent application (TEA) for use to determine eligibility of a condition for consideration in the OTC monograph system.

We developed the final guidance document entitled ''Time and Extent Applications for Nonprescription Drug Products'' (September 2011) (available from our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/time-and-extent-applications-nonprescription-drug-products*) to assist respondents with the information collection provisions found in the regulations. The guidance was issued consistent with our good guidance practice regulations at 21 CFR 10.115, which provide for comment at any time. The guidance explains what information an applicant should submit to the Agency to request that a drug product be included in the OTC drug monograph system. The guidance also discusses format and content elements, and the process for submitting information, consistent with the applicable regulations.

II. OTC Monograph Reform in the Coronavirus Aid, Relief, and Economic Security Act

The Coronavirus Aid, Relief, and Economic Security Act (CARES Act (Pub. L. 116–136, Stat. 281)) signed March 27, 2020, included provisions that govern the way certain OTC drugs are regulated in the United States. The CARES Act added section 505G to the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355h), which reforms and modernizes the OTC drug review process, including establishing new procedures for consideration of additions or changes to conditions covered in OTC monographs. As a result of these revised statutory provisions, we anticipate no submissions under § 330.14. Our OTC *Monographs@FDA* portal (*https://dps.fda.gov/omuf*) provides additional information about OTC monograph drugs and the OTC drug review process.

Consistent with section 505G(k)(3) of the FD&C Act, we plan to withdraw the regulations supporting the TEA provisions in part 330 and discontinue the related guidance document. When these actions occur, we will also request discontinuation of the information collection approved under OMB control number 0910–0688.

In the **Federal Register** of August 8, 2023 (88 FR 53497), 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
§ 330.14(c) and (d); Time and extent application and submission of information.	1	~1.29	1.29	861.78 hours (861 hours and 47 minutes).	1,112
§ 330.14(f) and (i); Submission of safety and effectiveness data, including data and information listed in § 330.10(a)(2), a listing of all serious adverse drug experiences that may have occurred (§ 330.14(f)(2)), and an official or proposed compendial monograph (§ 330.14(i)).					
§ 330.14(j) and (k); Submitter correspondence with FDA.					

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

As previously stated, as a result of the CARES Act statutory provisions described above, we anticipate no TEA submissions. For purposes of burden calculation, we assume one respondent as a placeholder. The burden we attribute to reporting activities is assumed to be distributed among the individual elements.

Our estimated burden for the information collection reflects, as a result of statutory requirements, a program change decrease of 6,894 hours and a corresponding decrease of 8 responses.

Dated: December 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–26985 Filed 12–7–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–E–5267]

Determination of Regulatory Review Period for Purposes of Patent Extension; Nuzyra Tablets (New Drug Application 209816)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) has determined the regulatory review period for Nuzyra Tablets (new drug application (NDA) 209816) and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect must submit either electronic or written comments and ask for a redetermination by February 6, 2024. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by June 5, 2024. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 6, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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–2019–E–5267 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; NUZYRA TABLETS (NDA 209816).'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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