4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-2851]

Agency Information Collection Activities; Proposed Collection; 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 Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on time and extent applications for nonprescription drug products.

DATES: Either electronic or written comments on the collection of information must be submitted by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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 [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. 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-2023-N-2851 for "Time and Extent Applications for Nonprescription Drug Products." 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 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.

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: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Time and Extent Applications for Nonprescription Drug Products

OMB Control Number 0910-0688--Extension

This information collection supports Agency regulations in 21 CFR part 330 regarding over-the-counter (OTC) human drugs and associated guidance. Specifically, FDA regulations in §330.14 (21 CFR 330.14) 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 monograph process if the conditions (e.g., active ingredients) meet certain "time and extent" criteria outlined in the regulations. The regulations allow a time and extent application (TEA) to be submitted to us by any party for our consideration to include new conditions in the OTC drug monograph system.

As explained in the guidance document entitled "Time and Extent Applications for Nonprescription Drug Products," (September 2011), when submitting a TEA for FDA review, the submitter must provide evidence as described in §330.14(c) demonstrating that the condition is eligible for inclusion in the monograph system. Section 330.14(d) specifies the number of copies and address for submission of a TEA. If we determine that a condition is eligible for inclusion in the OTC monograph, we will publish a notice of eligibility that requests the submission of data to demonstrate general recognition of the safety and effectiveness of the condition, and place the TEA on public display. The TEA submitter can then submit the safety and effectiveness information described in §330.14(f).

The guidance document explains what information an applicant should submit to FDA to request that a drug product be included in the OTC drug monograph system. The guidance document also discusses format and content elements as well as the submission process, consistent with the applicable regulations.

Consistent with applicable statutory requirements, the information is required to be submitted electronically.

Description of Respondents: Any interested party may submit a TEA for a change to the OTC monograph.

We estimate the burden of this information collection as follows:

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Section; Activity	No. of Respondents	No. 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. 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.	7	~1.29	9	861.78 hours	7,756

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

Our estimated burden reflects time needed for submitting applications, followup submissions of safety and efficacy data, and potential correspondence from submitters to FDA after a TEA has been submitted (e.g., requests for an informal conference, signed statements that the submission is complete, requests for FDA to withdraw TEA consideration). The burden we attribute to reporting activities is assumed to be distributed among the individual elements and averaged among respondents.

Based on a recent review of the information collection and submissions of TEAs since our last request for OMB approval, we have made no adjustments to the currently approved burden estimates.

Dated: August 3, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-16922 Filed: 8/7/2023 8:45 am; Publication Date: 8/8/2023]