



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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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 Burden¹

21 CFR Section; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours

<p>§ 330.14(c) and (d); Time and extent application and submission of information.</p> <p>§ 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)).</p> <p>§ 330.14(j) and (k); Submitter correspondence with FDA.</p>	1	~1.29	1.29	861.78 hours (861 hours and 47 minutes)	1,112
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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.