

holder submits an application for patent term extension to USPTO, USPTO requests information from FDA, including the length of the regulatory review period for the patented product. If USPTO concludes that the product is eligible for patent term extension, FDA publishes a notice that describes the length of the regulatory review period and the dates used to calculate that period. Interested parties may request, under § 60.24 (21 CFR 60.24), revision of the length of the regulatory review period, or may petition under § 60.30 (21 CFR 60.30) to reduce the regulatory review period by any time where marketing approval was not pursued with “due diligence.”

In 21 CFR 60.36(a) *due diligence* is defined as “that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period.” As provided in § 60.30(c), a due diligence petition “shall set forth sufficient facts, including dates, if possible, to merit an investigation by FDA of whether the applicant acted with due diligence.” Upon receipt of a due diligence petition, FDA reviews the petition and evaluates whether any change in the regulatory review period is necessary. If so, the corrected regulatory review period is published in the **Federal Register**. A

due diligence petitioner not satisfied with FDA’s decision regarding the petition may, under § 60.40 (21 CFR 60.40), request an informal hearing for reconsideration of the due diligence determination. Petitioners are likely to include persons or organizations having knowledge that FDA’s marketing permission for that product was not actively pursued throughout the regulatory review period. The information collection for which an extension of approval is being sought is the use of the statutorily created due diligence petition.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

21 CFR part 60—patent term restoration	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Revision of regulatory review period determinations; § 60.24 .....	4	1.25	5	100	500
Due diligence petitions; § 60.30 .....	1	1	1	50	50
Due diligence hearings; § 60.40 .....	1	1	1	10	10
<b>Total</b> .....					<b>560</b>

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

We base our estimates on our experience and the average number of requests for revision of regulatory review period determinations, due diligence petitions, and requests for hearing received in the past 3 years. We estimate that 4 respondents will submit an average of 1.25 requests for revision of the regulatory review period determinations annually, for a total of 5 requests received annually. We assume that it will take respondents 100 hours to prepare the factual and legal information necessary to submit a request for revision. Thus, we estimate a total reporting burden of 500 hours. We estimate that one or fewer due diligence petitions will be submitted annually and that will take a respondent 50 hours to prepare the petition, for a total of 50 hours. We estimate that one or fewer requests for hearing will be submitted annually and that it will take a respondent 10 hours to prepare the request for hearing, for a total of 10 hours.

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

**Grace R. Graham,**  
Deputy Commissioner for Policy, Legislation,  
and International Affairs.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2025-N-2652]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents**

**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 March 20, 2026.

**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 0910-0312. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Amber Barrett, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@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.

**Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents—21 CFR Part 1140**

OMB Control Number 0910-0312—Extension

This information collection supports FDA regulatory requirements contained in part 1140 (21 CFR part 1140) authorized under Chapter IX of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 9) and associated agency guidance. Regulations in part 1140 establish permissible forms of labeling and advertising for cigarettes or smokeless tobacco and include

reporting requirements directing persons to notify FDA if they intend to use a form of advertising or labeling that is not addressed in the regulations. Section 1140.30(a)(2) requires tobacco product manufacturers, distributors, and retailers to notify FDA if they intend to use advertising or labeling for cigarettes or smokeless tobacco in a medium that is not listed in section 1140.30(a)(1). The notice shall describe the medium and discuss the extent to which the advertising or labeling may be seen by persons younger than 18 years of age. The notifications must be made 30 days prior to the use of such media.

We allow electronic and written submission of these notifications. Respondents can mail notifications as prescribed in section 1140.30(a)(2) to FDA. Instructions providing clarification on how to format the notification may be found in the guidance document entitled "Compliance with Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents" (2013) (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/compliance-regulations-restricting-sale-and-distribution-cigarettes-and-smokeless-tobacco-protect>).

In the **Federal Register** of August 22, 2024 (90 FR 41085), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received four

comments. Two comments were responsive to the Paperwork Reduction Act (PRA) information collection topics solicited. Two comments were not responded to the PRA and will not be addressed here.

The comments generally supported FDA's collection of information. The comments supported FDA's maintaining oversight related to youth tobacco access through the regulatory provision related to this collection, encouraged the FDA to enhance transparency of this collection by clearly providing better explanation about how retailer and manufacturer data is analyzed and used for enforcement or policy interventions, and recommended expanding digital tools and providing plain language guidance materials in multiple languages to minimize administrative burden and help retailers understand submission requirements.

The comments also believed FDA has underestimated burden and suggested that there were ways to improve the collection by providing standardized submission templates, clearer definitions of unlisted media, illustrative examples, clarification of material changes requiring new notices, and different ways to provide supporting documentation. The comments believe FDA should provide target review and timelines and should implement an electronic submission portal, accept machine-readable attachments, allow consolidated annual or semiannual notification, provide a

fillable submission template, and establish a safe-harbor correction window.

In response, FDA thanks the commenters and agrees that this information collection has practical utility and is necessary for the proper performance of FDA's functions. Regarding burden estimates, FDA encourages detailed information be submitted and acknowledges burden for each respondent to the collection could vary and that it may take some respondents longer to complete the requirements than others. FDA tries to minimize burden by efficiently collecting information without compromising FDA's ability to identify and address violations by providing options to comply and allowing both electronic and mail submission of information. FDA believes that the average burden estimates per response are sufficient. FDA is always open to improve the quality, utility, and clarity of information we collect, and offers guidance regarding the types of information that should be included with a cover letter describing the information. FDA also provides a clear list of media that should be provided and options for providing supporting documentation and notes that any notification returned to the submitter is not intended to imply that prior approval is required before use of a medium.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
1140.30(a)(2)—Notification of other advertising or labeling medium .....	4	1	4	1	4
Total .....	.....	.....	.....	.....	4

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden hour estimates for this collection of information were based on submissions regarding cigarette and smokeless tobacco product advertising expenditures. FDA has received 12 such notifications to date since 2022. Based on a review of the information collection and the number of notifications received since 2022, FDA estimates that approximately four respondents will submit an annual notice of alternative advertising, and the Agency has estimated it should take one hour to provide such notice. Therefore, our estimated burden for the information collection reflects an

overall decrease of 21 hours and a corresponding decrease of 21 responses.

**Grace R. Graham,**  
Deputy Commissioner for Policy, Legislation,  
and International Affairs.  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2025-P-3575]

**Determination That TOLECTIN DS (Tolmetin Sodium) Capsule, Equivalent to 400 Milligrams Base, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.