

3. *The date the application was approved:* July 9, 2021. FDA has verified the applicant's claim that NDA 215341 was approved on July 9, 2021.

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 1,597 days of patent term extension.

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 24, 2023.
Lauren K. Roth,
Associate Commissioner for Policy.
 [FR Doc. 2023–26251 Filed 11–28–23; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2707]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; State Petitions for Exemption From Preemption

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 December 29, 2023.

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 0910–0277. 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.

State Petitions for Exemption From Preemption

OMB Control Number 0910–0277—*Extension*

This information collection supports FDA regulations. Under section 403A(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 343–1(b)), States may petition FDA for exemption from Federal preemption of State food labeling and standard-of-identity requirements. Section 100.1(c) (21 CFR 100.1(c)) provides prerequisites a petition must satisfy for an exemption from preemption. Section 100.1(d) sets forth the information a State is required to submit in such a petition. The petition must be submitted to the Dockets Management Staff. The information required under § 100.1 enables FDA to determine whether the State food labeling or standard-of-identity requirement satisfies the criteria of section 403A(b) of the FD&C Act for granting exemption from Federal preemption.

In the **Federal Register** of July 31, 2023 (88 FR 49469), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it was not responsive to the four information collection topics solicited.

Description of Respondents: The respondents to this collection of information are State and local governments who regulate food labeling and standards-of-identity.

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
100.1; petition for exemption from preemption	1	1	1	40	40

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

The reporting burden for § 100.1 is minimal because petitions for exemption from preemption are seldom submitted by States. In the next 3 years, we estimate that one or fewer petitions will be submitted annually.

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.
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