United States Food and Drug Administration

State Petitions for Exemptions from Preemption

OMB Control No. 0910-0277 - EXTENSION

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us, or we) regulations. Under section 403A(b) of the Federal Food, Drug, and Cosmetic Act (the 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 information required under § 100.1 enables us 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.

We therefore request extension of OMB approval of State petitions for exemptions from preemption found in 21 CFR 100.1 and discussed in this supporting statement.

2. Purpose and Use of the Information Collection

States seeking exemption from Federal preemption of State food labeling and standard-of-identity requirements may submit a petition to us under § 100.1. The information required under § 100.1 enables us to determine whether the State food labeling or standard-of-identify requirement satisfies the criteria of section 403A(b) of the FD&C Act for granting exemption from preemption.

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

3. Use of Improved Information Technology and Burden Reduction

The petition may be submitted by mail either as: (1) an original and one copy or (2) an original and a computer-readable disk containing the petition. Contents of the disk should be in a standard format. Petitions may be mailed or delivered to the Division of Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FDA currently does not accept e-mailed petitions. Petitions can be sent electronically to FDA via www.regulations.gov.

Section 100.1 does not prescribe the use of automated, electronic, mechanical, or other technological techniques of other forms of information technology as necessary for use by the States. States are free to use whatever form of information technology may best assist them in the development of their petition. We estimate that one-hundred percent (100%) of the petitions seeking exemption from Federal preemption of state food labeling and standard-of-identity requirements will be submitted electronically in the next three years.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

The provisions of this regulation are specific to State and local governments and are not applicable to small businesses. No small businesses will be involved in this information collection.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory and regulatory requirements.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances associated with this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), we published a 60-day notice for public comment in the *Federal Register* of July 31, 2023 (88 FR 49469). One comment was received, which was non-responsive to the four PRA topics, so we will not address them in this document.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments, or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

Data will be kept private to the extent allowed by law. In preparing this supporting statement, we consulted the FDA Privacy Office to ensure appropriate identification and handling of information collected.

Privacy Act

This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII collected is name, address, and phone number. FDA determined that although PII is collected, the collection is not subject to the Privacy Act of 1974, and the particular notice and other requirements of the Privacy Act of 1974 do not apply. Specifically, FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate webpage design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

Freedom of Information Act

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden					
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

The total burden for this information collection is 40 hours.

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.

12b. Annualized Cost Burden Estimate

The annual hour cost burden to respondents is approximately $3,611.20 per year. We estimate that the average hourly wage for the employee preparing and submitting a petition for an exemption from preemption would be equivalent to a GS-12/Step-1 level in the locality pay area of Washington-Baltimore in 2023, or $45.14/hour. Doubling this wage to account for overhead costs, we estimate the average hourly cost to respondents to be $90.28/hour. Thus, the overall estimated cost incurred by the respondents is $3,611.20 (40 burden hours x $90.28/hr).

Table 2.--Estimated Annual Cost Burden

21 CFR Section; Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
100.1; Preparing and submitting a petition for an exemption from preemption	40	$90.28	$3,611.20

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

There are no capital, start-up, operating, or maintenance costs associated with this collection.

14. Annualized Cost to the Federal Government

If a petition is submitted under § 100.1, we assume an annualized cost to the Federal government for the review and evaluation of a petition of $4,293.60. The cost is based on 40 hours of review and evaluation per year by an employee at a GS-13/Step-1 level in the locality pay area of Washington-Baltimore in 2023, or $53.67/hour, which equals $2,146.80 (40 hours x $53.67/hour).

To account for overhead, this cost is increased by 100 percent, making the estimated cost to the Federal government $4,293.60.

15. Explanation for Program Changes or Adjustments

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

16. Plans for Tabulation and Publication and Project Time Schedule

The information collected will not be published or tabulated.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA will display the OMB expiration date as required by 5 CFR 1320.8.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.