

# UNITED STATES FOOD & DRUG ADMINISTRATION

## State Petitions for Exemptions from Preemption

OMB Control No. 0910-0277

### 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 for exemption from Federal preemption of state food labeling and standard of identity requirements. Agency regulations in section 100.1(d) (21 CFR 100.1(d)) set forth the information a State is required to include in such a petition. The information required under § 100.1(d) 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 part 100, 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(d). The information required under § 100.1(d) 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. In the last three years, we have received one new petition from a state agency seeking exemption from Federal preemption.

*Description of Respondents:* Sates regulating food labeling and standards of identity. Respondents are state and local governments.

#### 3. Use of Improved Information Technology and Burden Reduction

Section 100.1(d) 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 twenty-five percent (25%) 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

Data collection occurs occasionally. There are no consequences to Federal program or policy activities if the information is not collected or is collected less frequently.

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 May 22, 2020 (85 FR 31190). No comments were received.

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

*Privacy Act.*

In preparing this supporting statement, our staff consulted with the FDA Privacy Office to ensure appropriate handling of any personally identifiable information (PII) that may be collected. In this ICR, a name is provided for contact purposes only. We have concluded, therefore, that information collected and stored is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, we (including our vendors or service providers acting on our behalf) do not use name or any other personal identifier to retrieve records associated with the information collection.

Additionally, no assurance of confidentiality is provided to respondents to the information collection. Consistent with 21 CFR § 100.1(e), public disclosure of state petitions will be governed by the rules specified in 21 CFR 10.20(j).

11. Justification for Sensitive Questions

This information collection does not involve any questions that are of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Cost

12a. *Annualized Hour Burden Estimate*

Table 1.--Estimated Annual Reporting Burden <sup>1</sup>					
21 CFR section; IC Activity	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
100.1(d); petitions requesting exemption from preemption for State or local requirements (form of petition)	1	1	1	40	40

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

The reporting burden for § 100.1(d) is minimal because petitions for exemption from preemption are seldom submitted by states. In the last 3 years, we have received one new petition for exemption from preemption; therefore, the agency estimates that one or fewer petitions will be submitted annually.

12b. *Annualized Cost Burden Estimate*

The annual hour cost burden to respondents is approximately \$3,309.60 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 2020, or \$41.37/hour. Doubling this wage to account for overhead costs, we estimate the average hourly cost to respondents to be \$82.74/hour. Thus, the overall estimated cost incurred by the respondents is \$3,309.60 (40 burden hours x \$82.74/hr. = \$3,309.60).

Table 2.--Estimated Annual Cost Burden

Activity	Total Burden Hours	Hourly Wage Rate	Total Costs
Preparing and submitting a petition for an exemption from preemption	40	\$82.74	\$3,309.60

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(d), we assume an annualized cost to the Federal government for the review and evaluation of a petition of \$3,935.20. The cost is based on 40 hours of review and evaluation per year by an employee at a GS-13/Step-1 salary rate of \$49.19/hr. for the Washington-Baltimore locality pay area for the year 2020 (40 hours x

\$49.19/hour = \$1,967.60). To account for overhead, this cost is increased by 100 percent, making the estimated cost to the Federal government \$3,935.20.

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 agency has no plans for publication of information from this information collection.

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

Approval to not display the expiration date for OMB approval of the information collection is not being sought.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.