State Petitions for Exemptions from Preemption

0910-0277

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

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(d) (21 CFR 100.1(d)) sets forth the information a State is required to submit in such a petition. The information required under § 100.1(d) 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.

FDA is requesting extension of OMB approval for the information collection requirements in the following citation:

21 CFR 100.1(d)- Reporting

Sets forth data requirements for State petitions requesting exemption from Federal preemption.

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 FDA under § 100.1(d). The information required under §100.1(d) enables FDA 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, FDA has received no petitions from State agencies seeking exemption from Federal preemption.

Description of Respondents: The respondents are States 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.

The agency estimates that about 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

No Federal duplication of information collection is likely because State petitions submitted under § 100.1(d) apply only to statutes and regulations administered by FDA. States would not be required to submit duplicative petitions with any other Federal agencies.

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.

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), FDA published a 60-day notice for public comment in the Federal Register of June 10, 2011 (76 FR 34082). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

FDA does not provide any payment or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

No assurance of confidentiality is given to petitioners. The regulation provides in §100.1(e) that 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 Costs

12 a. Annualized Hour Burden Estimate

Description of Respondents: The respondents are States regulating food labeling and standards of identity. Respondents are State and local governments.

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

Estimated Annual Reporting Burden[1]					
21 CFR Section	No. of Respondents	Number of Responses per Respondent	Total Annual Responses	Average Burden per Response (in Hours)[2]	Total Hours
100.1(d)	1	1	1	40	40

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Burden estimates of less than 1 hour are expressed as a fraction of an hour in the format "[number of minutes per response]/60".

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, FDA has not received any new petitions for exemption from preemption; therefore, the agency estimates that one or fewer petitions will be submitted annually. Although FDA has not received any new petitions for exemption from preemption in the last 3 years, it believes these information collection provisions should be extended to provide for the potential future need of a State or local government to petition for an exemption from preemption under the provisions of section 403(A) of the FD&C Act.

Estimated Annualized Cost for the Burden Hours
FDA estimates that the annualized hour burden cost to respondents for completion and submission will be insignificant.

12 b. Annualized Cost Burden Estimate

The annual hour cost burden to respondents is approximately $2870.40 per year. FDA estimates that the average hourly wage for the employee preparing and submitting a petition for an exemption from preemption would average approximately $35.88/hour. Doubling this wage to account for overhead costs, FDA estimates the average hourly cost to respondents to be $71.76/hour. Thus, the overall estimated cost incurred by the respondents is $2870.40 (40 burden hours x $71.76/hr = $2870.40).

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

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

14. Annualized Cost to Federal Government

In the event that a petition is submitted under §100.1(d), FDA estimates that the annualized cost to the Federal government for the review and evaluation of such a petition would be $1,706.40. The cost is estimated as being equivalent to 40 hours of review and evaluation per year at a GS-13/Step-1 salary rate of $42.66/hr for the Washington-Baltimore locality pay area for the year 2011 (40 hours x $42.66/hour = $1,706.40).

15. Explanation for Program Changes or Adjustments

There are no program changes or adjustments.

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.