

SUPPORTING STATEMENT

State Petitions for Exemption from Preemption (21 CFR 100.1(d))

OMB No. 0910-0277

A. JUSTIFICATION

1. Necessity for the Information Collection

The Nutrition Labeling and Education Act of 1990 (the 1990 amendments) amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 403A(a) (21 U.S.C. 343-1(a)) to provide for national uniform nutrition labeling by providing for the preemption of certain types of State and local labeling requirements that are not identical to applicable Federal requirements; e.g., food standards, nutrition labeling, health claims, and ingredient declaration requirements (Attachment A).

The 1990 amendments also added section 403A(b)(21 U.S.C. 343-1(b)) that permits the States to petition the Food and Drug Administration (FDA) for exemption of State requirements from Federal preemption of State food labeling and standard of identity requirements. FDA may grant the petition for exemption if the State shows that the State requirement (1) would not cause any food to be in violation of any applicable requirement under Federal law, (2) would not unduly burden interstate commerce, and (3) is designed to address a particular need for information which need is not met by the requirements of the sections referred to in section 403A(a) of the act (Attachment A).

FDA has established procedural regulations in 21 CFR Part 100 pertaining to the submission of State petitions requesting exemption from Federal preemption. These procedural regulations address the content and substance of the information that the State is required to supply to meet the statutory requirements for obtaining an exemption from preemption.

This is a request for extension by OMB of its approval of the information collection requirements in the following citation (Attachment B):

21 CFR 100.1(d)- Reporting

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

2. How, by Whom, and for What Purpose the Information is Used

Section 403A(b) of the act provides for the submission from States of petitions for exemption from preemption. The information provided in a State petition for exemption from preemption submitted under the provisions of §100.1(d)(21 CFR 100.1(d)) will be used by FDA to determine whether the petition satisfies the criteria of section 403A(b) for granting exemption from preemption. The consequences of not specifying in §100.1(d) the information to be collected would be a reduced likelihood that a petition for exemption from preemption would meet the statutory requirements for obtaining an exemption.

The petition provisions of §100.1(d) have been in effect since February 5, 1993. FDA has received eight petitions from State agencies seeking exemption from preemption of Federal provisions for certain local requirements. Four of those petitions have subsequently been withdrawn. The remaining four continue under agency review and consideration.

3. Consideration of Information Technology

The regulation for State petitions for exemption from preemption 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.

4. Identification of Duplication and Similar Information Already Available

An exemption granted under §100.1 is granted only to the petitioning State. Exemption from preemption is largely based on an evaluation of a unique situation within a State. It is possible that a situation could arise that is more national in scope that would require duplicate petitions pertaining to the same subject submitted by one or more States. In such a case, the agency would consider amendment of the Federal requirement because the action requested would be more universal than that envisioned by Congress in providing the exemption. Because the preemption provisions of section 403A(a) apply only to statutes and regulations administered by FDA, there is no likelihood of Federal duplication of effort.

5. Small Business

The provisions of this regulation are specific to State and local governments and are not applicable to small businesses.

6. Describe the Consequences If the Data Were Collected less Frequently

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

7. Special Circumstances

None of the requirements are inconsistent with the guidelines in 5 CFR 1320.5.

8. Outside Consultation

In accordance with 5 CFR 1320.8(d), on Friday, June 4, 1999 (64 30037) a 60 Day notice for public comment (Attachment C) was published in the Federal Register. One comment was received that was supportive of the proposal and encouraged FDA to continue this information collection request.

9. Gifts

This information collection does not provide for payment or gifts to respondents.

10. Confidentiality

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. Sensitive Questions

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

12. Respondent Hour Burden and Annualized Burden Hour Costs Estimates

Burden Hours.

| Estimated Annual Reporting Burden ¹ | | | | | |
|--|--------------------|-------------------------------|------------------------|--------------------|-------------|
| 21 CF Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
| 100.1(d) | 1 | 1 | 1 | 40 | 40 |

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

FDA expects that the burden hours for this information collection in the future will be insignificant. Petitions for exemption from preemption have infrequently been submitted in the recent past; none have been submitted since publication on January 6, 1993, of the final

regulations implementing section 403(q) and (r) .

Although FDA believes that the burden will be insignificant, 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)(b) of the act.

Estimated Annualized Cost for the Burden Hours.

FDA estimates annualized hour burden cost to respondents for completion and submission will be insignificant.

13. Estimated Costs Burden to Respondents

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

14. Annualized Costs to Government

The annualized cost to the Federal government for the review and evaluation of petitions submitted under §100.1(d) is \$5250. The cost is estimated as being equivalent to a GS-13 salary (\$25/hr) and overhead as being equal to salary or $(40 \text{ hrs} \times \$25/\text{hr} (\text{salary}) = \$5,000 + \$5,000 (\text{overhead}) = \5250).

15. Changes in Burden

The decrease in hour burden is due to the reduction in the number of petitions submitted by the States.

16. Statistical Analysis, Publication Plans, and Schedule

The information obtained from this data collection will not be published.

17. Approval Not to Display Expiration Date

No approval is requested.

18. Exception to Certification Statement

No exceptions requested.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

This collection of information does not employ statistical methods.