STATE PETITIONS FOR EXEMPTION FROM PREEMPTION
OMB No. 0910-0277

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

Under section 403A(b) of the Federal Food, Drug, and Cosmetic Act (the 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 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) for granting exemption from preemption. In the last three years, FDA has received no petitions from State agencies seeking exemption from Federal preemption.

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.

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

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

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

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 March 4, 2008 (73 FR 11648). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

This information collection does not provide for 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 of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

Description of Respondents: respondents to this collection of information are State governments.

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

Estimated Annual Reporting Burden[1]					
21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	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.

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 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.

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no capital costs or operating and 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 $1,590. 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 $39.75/hr for the Washington-Baltimore locality pay area for the year 2008 (40 hours x $39.75/hour = $1,590).

15. Explanation for Program Changes or Adjustments

The hour burden is unchanged.

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

No exceptions are requested.