STATE ENFORCEMENT NOTIFICATIONS

OMB No. 0910-0275

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

Section 310(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 337(b)) authorizes States to enforce certain sections of the act in their own names, but provides that States must notify FDA before doing so. Section 100.2(d) (21 CFR 100.2 (d)) sets forth the information that a State must provide to FDA in a letter of notification when it intends to take enforcement action under the act against a particular food located in the State. The information required under § 100.2(d) will enable FDA to identify the food against which the State intends to take action and advise the State whether Federal action has been taken against it. With certain narrow exceptions, Federal enforcement action precludes State action under the act.

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

21 CFR 100.2(d) - Reporting
Describes the information to be in a notification from a State advising FDA of the State's intent to initiate enforcement of certain requirements of the act.

2. Purpose and Use of the Information Collection

Section 310(b) of the act provides that States must submit notice to FDA before taking action to enforce certain provisions of the food misbranding provisions of the act. This information will be used by the agency in reaching a conclusion as to whether Federal action is being or will be taken against the same product that is under consideration for action by the State.

3. Use of Improved Information Technology and Burden Reduction

The regulation for State notices of intended enforcement actions does not specifically prescribe the use of automated, electronic, mechanical or other technological techniques or other forms of information technology as necessary for use by the States. States are free to use whatever forms of information technology may best assist them in their development of a notice.

4. Efforts to Identify Duplication and Use of Similar Information

The notification provisions of 100.2(d) eliminate the possibility that State action against a food for violation of the Federal law would be duplicated by FDA. Because the enforcement provisions are limited to labeling provisions of the act that are enforced by FDA, there is no likelihood of duplication by other Federal agencies.

5. Impact on Small Businesses or Other Small Entities

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The provisions of this regulation are specific to State 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. Under section 310(b) of the act, a State's standing to bring an action under the act is predicated on the State submitting a letter of notification to FDA. Therefore, if the letter of notification is not submitted, the State cannot institute an action to enforce a provision of the act.

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

There are no special circumstances associated with this information collection.

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

In accordance with 5 CFR 1320.8(d), on July 18, 2008 (73 FR 41360), a 60-day notice for public comment was published in the Federal Register. FDA received one comment, which was not responsive to the comment request.

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

State notifications to FDA under section 310(b) of the act will contain information compiled for law enforcement purposes and may contain trade secrets or confidential commercial or financial information. Accordingly, section 100.2(i) provides that information contained in the required notification will be exempt from public disclosure to the same extent to which such information would be exempt under 21 CFR 20.61, 20.64, and 20.88.

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

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

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
100.2(d)	1	1	1	10	10

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

The estimated reporting burden for § 100.2(d) is minimal because enforcement notifications are seldom used by States. During the last 3 years, FDA has not received any new enforcement notifications; therefore, the agency estimates that one or fewer notifications will be submitted annually. Although FDA has not received any new enforcement notifications in the last three years, it believes these information collection provisions should be extended to provide for the potential future need of a State government to submit enforcement notifications informing FDA when it intends to take enforcement action under the act against a particular food located in the State.

Estimated Annualized Cost for the Burden Hours

FDA estimates the annualized burden hour cost to a respondent for completion and submission of an enforcement notification to be approximately $668. FDA estimates that a state administrator's average wage to be that of a Federal government employee at the GS-12/Step-1 rate for the Washington-Baltimore locality pay area for the year 2008, which makes the annual wage cost for completion and submission approximately $334 (10 hours x $33.43 per hour). To account for overhead, this cost is increased by 100 percent, making the total estimated burden hour cost to the respondent $668.

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

FDA estimates that the annualized cost to the Federal government for the review and evaluation of enforcement notifications submitted under section 100.2(d) is approximately $3,180. This is based on the assumption that review and evaluation by a Federal employee will take about 40 hours per notification at $39.75 per hour (the GS-13/Step-1 salary rate for the Washington-Baltimore locality pay area for the year 2008). Thus, the wage cost to the Federal government for review and evaluation of notifications would be $1,590 (40 hours x $ 39.75 per hour). To account for overhead, this cost is increased by 100 percent, making the total estimated cost to the federal government $3,180.

15. Explanation for Program Changes or Adjustments

There is no change in the burden estimate.

16. Plans for Tabulation and Publication and Project Time Schedule

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

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

No approval is requested.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

N/A