

SUPPORTING STATEMENT
State Enforcement Notifications (21 CFR 100.2(d))
OMB No. 0910-0275

A. JUSTIFICATION

1. Necessity for the Information Collection

Section 310(b) (21 U.S.C. 337(b)) of the Federal Food, Drug, and Cosmetic Act (the act) authorizes States to enforce certain sections of the act in their own names (Attachment A). A State's ability to exercise this authority is predicated upon the State giving notice to the FDA that it intends to bring such proceeding 30 days before instituting action. FDA has established procedural regulations in 21 CFR Part 100 pertaining to the submission of State enforcement notifications. 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 (Attachment B).

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

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

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. Identification of Duplication and Similar Information Already Available

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. Small Businesses

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

6. Consequences if 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. 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

There are no special circumstances associated with this information collection.

8. Outside Consultation

In accordance with 5 CFR 1320.8(d), on June 20, 2005 (70 FR 35446), a 60-day notice for public comment (Attachment C) was published in the Federal Register. No comments were received.

9. Gifts

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

10. Confidentiality

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. 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 Burden¹					
21 CFR Section	No. of Respondents	Annual Frequency of Response	Total Annual Responses	Hours per Response	Total Hours
100.2(d)	1	1	1	10	10

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. In the last three years, FDA has received no enforcement notifications from State agencies. Although FDA believes that the burden will be insignificant, it believes this information collection provision should be extended to provide for the potential future need of a State government to submit enforcement notifications under the provisions of section 310(b) of the act. Because 100.2(d) implements a statutory information collection requirement, only the additional burden attributable to the regulation has been included in the estimate.

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 \$618. The state administrators average wage is about \$30.92 per hour, which makes the annual wage cost for completion and submission approximately \$309 (10 hours x \$30.92 per hour). To account for overhead, this cost is increased by 100 percent, making the total estimated burden hour cost to the respondent \$618.

13. Annual Cost Burden to Respondent

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

14. Annualized Cost to the 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 \$2,866. This is based on the assumption that review and evaluation by a Federal employee will take about 40 hours per notification at \$ 35.83 per hour (theGS-13/Step-1 salary rate for the Washington-Baltimore locality pay area for the year 2005). Thus, the wage cost to the Federal government for review and evaluation of notifications would be \$1,433 (40 hours x \$ 35.83 per hour). To account for overhead, this cost is

increased by 100 percent, making the total estimated cost to the federal government \$2,866.

15. Changes or Adjustments in Burden

There is no change in the burden estimate.

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 the Certification Statement Identified in Item 19.

No exceptions to the certification statement identified in item 19 of the instructions for completing OMB form 83-I have been identified.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

This collection of information does not employ statistical methods.