United States Food and Drug Administration
State Enforcement Notifications

OMB Control No. 0910-0275

SUPPORTING STATEMENT **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us or we) regulations. Section 403A(b) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act, the act) provides that, where a State requirement has been preempted under section 403A(a) of the act, the State may petition the agency for an exemption from preemption. If the Food and Drug Administration (FDA, us or we) finds that the State requirement will not cause any food to be in violation of any applicable requirement under Federal law, will not unduly burden interstate commerce, and is designed to address a particular need for information that is not met by the preemptive Federal requirement, the exemption from preemption may be granted. A State may also bring civil enforcement proceedings on its on behalf under for violations of certain sections of the act in accordance with Section 310.

Regulations found at 21 CFR Part 100 establish submission and consideration requirements for both petitions under section 403A(a) of the act, and notifications prescribed under Section 310. Information collection provisions associated with preemption petitions are found in 21 CFR Part 100.1 and are approved under OMB Control No. 0910-0277. Regulations at 21 CFR 100.2 set forth notification requirements associated with State enforcement proceedings and explain certain limitations. With narrow exceptions, Federal enforcement action precludes State action under the FD&C Act.

We therefore request extension of OMB approval for the information collection provisions found under 21 CFR Part 100.2: *State Enforcement of Federal Regulations*, and discussed in this supporting statement.

2. Purpose and Use of the Information Collection

Section 310(b) of the FD&C Act provides that States must give notice to FDA before taking action to enforce certain provisions of the food misbranding provisions of the FD&C 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.

Description of Respondents: The respondents are State governments that enforce certain sections of the FD&C Act relating to misbranding of foods and food standards of identity.

3. Use of Improved Information Technology and Burden Reduction

The regulation (21 CFR 100.2) for State notices of 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. We estimate any notifications received in the next three years will be submitted electronically.

4. Efforts to Identify Duplication and Use of Similar Information

Notifications under 21 CFR 100.2(d) should prevent State duplication of an FDA enforcement action against a food for certain violations of the FD&C Act. Also, we note that provisions set forth under 21 CFR 100.1 and covered under OMB Control No. 0910-0277 may be appropriately consolidated with this information collection. We are otherwise unaware of duplication.

5. Impact on Small Businesses or Other Small Entities

The provisions of 21 CFR 100.2(d) are specific to State governments and are not applicable to small businesses. FDA estimates that zero percent (0%) of respondents are 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 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), FDA published a 60-day notice for public comment in the Federal Register of February 7, 2018 (83 FR 5438). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

FDA does not provide any payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

State notification letters submitted to FDA under section 310(b) of the FD&C Act will contain information compiled for law enforcement purposes and may contain trade

secrets or confidential commercial or financial information. Accordingly, 21 CFR 100.2(i) provides that information contained in the required notification letters 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. This information is also safeguarded by section 301(j) of the FD&C Act and would be protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)).

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

12a. Annualized Hour Burden Estimate

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

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

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden 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 21 CFR 100.2(d) is minimal because enforcement notifications are seldom used by States. During the last 3 years, we have not received any new enforcement notifications; therefore, we estimate that one or fewer notifications will be submitted annually.

Although we have not received any new enforcement notifications in the last 3 years, we believe these information collection provisions should be extended to provide for the potential future need of a State government to submit enforcement notifications informing us when it intends to take enforcement action under the FD&C Act against a particular food located in the State.

12b. Annualized Cost Burden Estimate

FDA estimates the annualized burden hour cost to a respondent for completion and submission of an enforcement notification to be approximately $780. 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 2018, which makes the annual wage cost for completion and submission approximately $390 (10 hours x $39.07 per hour). To account for overhead, this cost is increased by 100 percent, making the total estimated burden hour cost to the respondent $780.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
State administrator	10	$78.00	$780

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

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

14. Annualized Cost to the Federal Government

    We estimate an annualized cost to the Federal government attributable to the review and evaluation of enforcement notifications submitted under section 21 CFR 100.2(d) to be approximately $3,716.80. This figure assumes that review and evaluation by a Federal employee takes about 40 hours per notification at $46.46 per hour (the GS-13/Step-1 salary rate for the Washington- Baltimore locality pay area for the year 2018). However, as stated previously, no notifications have been received since last OMB review of the information collection.

15. Explanation for Program Changes or Adjustments

    We retain the currently approved burden estimate for the information collection.

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 to not display the expiration date of OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

    There are no exceptions to the certification.