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 310(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 337(b)) authorizes a State to enforce certain sections of the FD&C Act in their own name and within their own jurisdiction. However, before doing so, a State must provide notice to FDA according to 21 CFR 100.2. The information required in a letter of notification under § 100.2(d) enables us to identify the food against which a State intends to take action and to advise that State whether Federal enforcement action against the food has been taken or is in process. With certain 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 100.2: *State Enforcement of Federal Regulations*.

2. Purpose and Use of the Information Collection

   Section 310(b) of the FD&C Act provides that States must give notice to us 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 (e.g., 100%) in the next three years will be submitted electronically.

4. Efforts to Identify Duplication and Use of Similar Information

   We are unaware of duplicative information collection. Notifications provisions of 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. The notification provisions are limited to certain labeling requirements of the FD&C Act that are enforced by FDA. Because Federal enforcement of

these provisions is exclusive to FDA, there is no likelihood of enforcement duplication by other Federal agencies.

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. We estimate that none of the 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), we published a 60-day notice for public comment in the *Federal Register* of December 17, 2020 (85 FR 81932). 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)).

    Privacy Act

    In preparing this supporting statement, we consulted with our Privacy Office to ensure appropriate handling of information collected.

    This ICR does not collect personally identifiable information (PII) or information of a personal nature. This information collection supports an FDA regulation, 21 CFR 100.2 as well as section 403A(b) of the FD&C Act.

    We further determined that this collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, we (including vendors or service providers acting on behalf of FDA) do not use name or any other personal identifier to retrieve records from the information collected.

Under FOIA (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). We will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

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 Cost

12a. Annualized Hour Burden Estimate

We estimate 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 $835.60. 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 2021, which makes the annual wage cost for completion and submission approximately $417.80 (10 hours x $41.78 per hour). To account for overhead, this cost is increased by 100 percent, making the total estimated burden hour cost to the respondent $835.60.

Table 2.--Annual Cost Burden Estimate

Type of Respondent	Total Burden Hours	Fully Loaded Hourly Wage Rate	Total Respondent Costs
State administrator	10	$83.56	$835.60

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or 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 $3,974.40. This figure assumes that review and evaluation by a Federal employee takes about 40 hours per notification at $49.68 per hour (the GS-13/Step-1 salary rate for the Washington- Baltimore locality pay area for the year 2021). To account for overhead, we have doubled the hourly rate to $99.36, which brings the annualized cost to $3,974.40 (40 hours x $99.36/hour).

However, as stated previously, no notifications have been received since the last OMB review of the information collection.

15. Explanation for Program Changes or Adjustments

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

16. Plans for Tabulation and Publication and Project Time Schedule

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

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.