UNITED STATES FOOD AND DRUG ADMINISTRATION

Food Contact Substance Notification Program

OMB Control No. 0910-0495 - Revision
RIN 0910-AI01 – Final Rule

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA or we) rulemaking that will revise applicable procedures found in 21 CFR part 170, subpart D by which we determine that a premarket notification for a food contact substance (FCN) is no longer effective. The final rule will, among other things, ensure that manufacturers or suppliers have the opportunity to provide input before FDA determines that an FCN is no longer effective. The final rule also will permit providing additional reasons that could be the basis for FDA to determine that an FCN is no longer effective. The changes are intended to better enable FDA to respond to new information on the safety and use of food contact substances, as well as manufacturers' business decisions, which will also improve our FCN program's efficiency.

We therefore request OMB approval of the reporting provisions applicable to 21 CFR 170.105, as revised by the rulemaking and discussed in this supporting statement.

2. Purpose and Use of the Information Collection

We will review relevant information and data submitted by the affected manufacturer or supplier of the food contact substance in response to new information that their FCN may no longer be effective. We may determine that the specified FCN may no longer be effective for its intended use based on either: (1) not safe for its intended use; or (2) stopped being produced, supplied, or used as a food contact substance for its intended use; or (3) authorized by a food additive regulation; or (4) covered by a threshold of regulation exemption.

Description of Respondents: Respondents to the information collection are manufacturers and suppliers of food contact substances sold in the United States. Respondents are from the private sector (for-profit businesses).

3. Use of Improved Information Technology and Burden Reduction

FCNs and formulations contain summaries of data and narrative text. FDA currently accepts this information electronically via the CFSAN Online Submission Module (COSM) or electronic media (such as: CD ROM, DVD). We expect the requests for withdrawal and responses to be submitted the same way. The agency estimates that all withdrawal requests and responses to it (100%) will be submitted electronically over the next three years.

In addition, to avoid unnecessary duplication for individual submissions, existing data would be used whenever possible by FDA in evaluating notifications for food contact substances. We use an image-based document management system to permit the agency to track effective notifications and to permit the agency to determine if a food contact substance has already been reviewed by the agency.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. We continue to work with EPA and USDA to eliminate areas of duplicate data collection and evaluation. USDA eliminated its approval processes for components of food contact materials that duplicated FDA's processes. In addition, the Food Quality Protection Act of 1996 gave sole jurisdiction to EPA for certain substances formerly regulated by FDA as food additives and by EPA as pesticide chemicals. Currently there is no significant duplication of data collection and evaluation for food contact substances among Federal agencies with jurisdiction. We also maintain on the FDA Internet site a list of effective notifications. We will be the only agency reviewing withdrawal requests and their corresponding responses.

5. Impact on Small Businesses or Other Small Entities

The information collection poses no undue burden on small entities. We estimate that fifty percent (50%) of respondents are small businesses. We believe that the revised requirements will help simplify premarket notification processes for small businesses who voluntarily request to withdraw an FCN instead of submitting data or other information demonstrating an FCN is no longer safe for its intended use.

Additionally, whenever possible, individual assistance will be given to requesters to minimize the likelihood that unnecessary work is performed. We aid small businesses in complying with its requirements through the agency's Regional Small Business Representatives and through the scientific and administrative staffs within the agency.

We also provide small business assistance on the agency's website at https://www.fda.gov/industry/small-business-assistance.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with applicable statutory and regulatory authorities.

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

There are no special circumstances associated with this collection of information.

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

In the *Federal Register* of January 26, 2022 (87 FR 3949), Docket No. FDA-2021-N-0403, we published a proposed rule inviting public comment on the proposed information collection. Our

responses to the comments are included in Section IV of the final rule, publishing in the *Federal Register* of March 22, 2024; docket no. FDA-2021-N-0403.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

Consistent with 5 CFR 1320.5(d)(2)(vii) and agency regulations in 21 CFR § 20.20, data will be kept private to the extent allowed by law:

The Freedom of Information Act

Under the Freedom of Information Act (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)). FDA 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.

We expect that responses to withdrawal requests may contain trade secret and commercial confidential information. As a result, all files will be maintained in a secured area. A manufacturer or supplier of the food contact substance may choose to provide a redacted copy of their response, identifying information that the submitter views as trade secret or as confidential commercial or financial information.

Only information that is releasable under the agency's regulations in 21 CFR part 20 would be released to the public. This information is also safeguarded by section 301(j) of the FD&C Act and would be protected from disclosure under FOIA under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)).

The Privacy Act of 1974

This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII submitted via COSM is name, title, address, email address, telephone number, and fax telephone number. FDA determined that although PII is collected, it is not subject to the Privacy Act of 1974, and the particular submission and other requirements of the Privacy Act do not apply. Specifically, the contractor or FDA do not use name or any other personal identifier to routinely retrieve records from the information collected. Through appropriate form design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

21 CFR Section; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
170.105(a); Manufacturer or supplier responds to FDA by providing a written response and additional data or information to demonstrate that the FCN should continue to be effective	2	1	2	75	150
170.105 (a)(2)(i); Manufacturer or supplier requests that FDA determine that the FCN should no longer be effective based on non-safety reasons	5	1	5	2	10
Total					160

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

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

We will inform the affected manufacturers or suppliers of the specified FCN about data or other information that their food contact substance may: (1) not be safe for its intended use; or (2) have stopped being produced, supplied, or used as a food contact substance for its intended use; or (3) be authorized by a food additive regulation; or (4) be covered by a threshold of regulation exemption. As such, we may determine that the specified FCN may no longer be effective for its intended use unless the affected manufacturer or supplier provides additional data or information to demonstrate that the FCN should continue to be effective. In row 1, we estimate that, annually, 2 respondents will each spend about 75 hours preparing a written response followed by submission of additional data or information to demonstrate that the FCN should continue to be effective for a total of 150 hours (2 respondents x 75 hours). In the existing information collection for our Food Contact Substance Notification Program (OMB control no. 0910-0495; 87 FR 7190 (February 8, 2022)), we estimate that it may take up to 150 hours to prepare and submit an FCN depending on the complexity of the submittal. We assume the time to prepare a response will take about half the time of the initial submittal because the manufacturer or supplier should already have compiled and have access to most, if not all the information demonstrating that their FCN should continue to be effective and remains safe for its intended use.

The final rule will allow a manufacturer or supplier to request that FDA determine that their FCN is no longer effective on the basis that the manufacturer or supplier no longer produces, supplies, or uses the food contact substance for the intended use. We believe a manufacturer or supplier will not need much time to prepare such a request as it should already have access to information that it has or intends to no longer produce, supply, or use the food contact substance for the intended use. Based on the Final Regulatory Impact Analysis for the final rule, we estimate that 5 respondents will voluntarily request that we determine that their FCN is no longer effective. Accordingly, in row 2, we estimate that 5 respondents will each submit 1 request to us per year with each request taking 2 hours to prepare for a total of about 10 hours (2 respondents x 5 hours).

12b. Annualized Cost Burden Estimate

Gathering the information discussed here and providing it to the agency requires a team of professional employees, which may include toxicologists, chemists, environmental scientists, and lawyers. We estimate that the average hourly wage for these employees would be equivalent to a GS-14/Step-1 level in the locality pay area of Washington-Baltimore in 2023, approximately $63.43/hour. Doubling this wage to account for overhead costs, we estimate the average hourly cost to respondents to be $126.86/hour. Thus, the overall estimated cost incurred by the respondents is $20,297.60 (160 burden hours x $126.86/hour). This is an update from our proposed rule in which we use 2020 wage figures.

Table 2.--Estimated Annual Cost Burden

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Manufacturers and suppliers of food contact substances	160	$126.86	$20.297.60

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 collection.

14. Annualized Cost to the Federal Government

We have updated our estimate of Federal costs reported for the proposed rule based on updated wage rates. Assuming that review of withdrawal requests and responses will take 1,500 hours per submittal, we calculate the hourly cost for review and evaluation to be $63.43 per hour, the GS-14/Step-1 rate for the Washington-Baltimore locality pay area for the year 2023. To account for overhead, this cost is increased by 100 percent, making the total cost $126.86 per hour. We estimate the cost to the Federal government for the review and determinations to be $190,290 per review ($126.86/hour x 1,500 hours) and that we will review and make determinations for 7 submittals. Thus, we estimate the total annual cost to the Federal government to be $1,332,030 ($190,290/review x 7 submittals).

15. Explanation for Program Changes or Adjustments

This information collection reflects program changes resulting from rulemaking. As a result, we have adjusted our estimate adding 160 hours and 7 responses annually to reflect information collection associated with new regulatory requirements. We have also updated cost estimates previously proffered to reflect 2023 data.

16. Plans for Tabulation and Publication and Project Time Schedule

No statistics from the information obtained from this data collection will be published. However, a list of effective notifications is made available on the FDA website. This list includes the notifier, the identity of the food contact substance, the effective date of the notification, as well as any appropriate limitations on the use of the food contact substance. It does not include any confidential information. The FCN inventory will be revised dependent on FDA's determination that an FCN is no longer effective. Along with the current inventory of

effective FCNs, FDA intends to establish and maintain a list of FCNs that are no longer effective and the reason for the FDA's determination on its website.

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

There are no reasons why display of the expiration date for OMB approval of the information collection would be inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.