

United States Food and Drug Administration

Submission of Petitions:
Food Additive, Color Additive (Including Labeling), Submission of
Information to a Master File in Support of Petitions, and
Electronic Submission Using Food and Drug Administration Form 3503

OMB Control No. 0910-0016

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA or we) regulations as discussed below:

Food Additive Petitions and Labeling Requirements

Section 409(a) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 348(a)) provides that a food additive shall be deemed to be unsafe, unless: (1) The additive and its use, or intended use, are in conformity with a regulation issued under section 409 of the FD&C Act that describes the condition(s) under which the additive may be safely used; (2) the additive and its use, or intended use, conform to the terms of an exemption for investigational use; or (3) a food contact notification submitted under section 409(h) of the FD&C Act is effective. Food additive petitions (FAPs) are submitted by individuals or companies to obtain approval of a new food additive or to amend the conditions of use permitted under an existing food additive regulation. Section 171.1 of FDA's regulations (21 CFR 171.1) specifies the information that a petitioner must submit in order to establish that the proposed use of a food additive is safe and to secure the publication of a food additive regulation describing the conditions under which the additive may be safely used. Parts 172, 173, 179, and 180 (21 CFR parts 172, 173, 179, and 180) contain labeling requirements for certain food additives to ensure their safe use. The labeling regulations are considered by FDA to be cross-referenced to § 171.1.

Color Additive Petitions and Labeling Requirements

Section 721(a) of the FD&C Act (21 U.S.C. 379e(a)) provides that a color additive shall be deemed to be unsafe unless the additive and its use are in conformity with a regulation that describes the condition(s) under which the additive may safely be used, or the additive and its use conform to the terms of an exemption for investigational use issued under section 721(f) of the FD&C Act. Color additive petitions (CAPs) are submitted by individuals or companies to obtain approval of a new color additive or a change in the conditions of use permitted for a color additive that is already approved. Section 71.1 of our regulations (21 CFR 71.1) specifies the information that a petitioner must submit to establish the safety of a color additive and to secure the issuance of a regulation permitting its use. FDA's color additive labeling requirements in § 70.25 (21 CFR 70.25) require that color additives that are to be used in food, drugs, medical devices, or cosmetics be labeled with sufficient information to ensure their safe use.

FDA Form 3503 and Master File

Respondents may transmit FAP or CAP regulatory submissions in electronic format or paper format to the Office of Food Additive Safety in the Center for Food Safety and Applied Nutrition using Form FDA 3503. Form FDA 3503 helps the respondent organize their submission to focus on the information needed for FDA's safety review. Form FDA 3503 can also be used to organize information within a master file submitted in support of petitions according to the items listed on the form. Master files can be used as repositories for information that can be referenced in multiple submissions to the agency, thus minimizing paperwork burden for food and color additive approvals.

We improved the information collection by using the CFSAN Online Submission Module (COSM). COSM provides a real-time user interface process that assists respondents in preparing and making submissions to CFSAN. COSM is a web-based tool that supports electronic submissions, thereby eliminating the need for printing and mailing of paper submissions. COSM is available 24 hours a day and 7 days a week. Further information about COSM, including user instruction, is available on the internet at: <https://www.fda.gov/food/registration-food-facilities-and-other-submissions/cfsan-online-submission-module-cosm>.

Therefore, we request extension of OMB approval of the information collection provisions found in this collection of information and in Form FDA 3503.

2. Purpose and Use of the Information Collection

FDA scientific personnel review FAPs to ensure the safety of the intended use of the additive in or on food, or that may be present in food as a result of its use in articles that contact food. Likewise, FDA personnel review CAPs to ensure the safety of the color additive prior to its use in food, drugs, medical devices, or cosmetics.

Description of Respondents: Respondents are businesses engaged in the manufacture or sale of food, food ingredients, color additives, or substances used in materials that come into contact with food. Respondents are typically from the private sector (for-profit businesses).

3. Use of Improved Information Technology and Burden Reduction

We are using our electronic submission system, COSM. Respondents may transmit regulatory submissions in electronic format via COSM or paper format on Form FDA 3503. Electronic Form FDA 3503 also can be used to organize information within a master file submitted in support of petitions according to the items listed on the form.

We estimate that 80% of the respondents will electronically submit the information being collected via COSM or on a physical media (e.g., CD-ROM or DVD).

4. Efforts to Identify Duplication and Use of Similar Information

We continue to work with Environmental Protection Agency (EPA) and the U.S. Department of Agriculture (USDA) to eliminate areas of duplicate data collection and evaluation. There is no duplication of FDA labeling requirements by other U.S. government agencies. Memoranda of understanding have been reached with EPA in the areas of pesticides and water treatment. EPA

establishes a tolerance, or exemption from tolerance, for pesticide chemicals and residues of such chemicals in food, and we enforce the tolerance or exemption.

Under the Meat and Poultry Inspection Acts (21 U.S.C. 601(m)(2) and 21 U.S.C. 453(g)(2)), the USDA Food Safety and Inspection Service (FSIS) has regulatory authority to determine the suitability and regulate the use of ingredients and sources of radiation in or on meat and poultry products in federally inspected facilities. FDA's regulations listed in §§ 71.1 and 171.1 permit an efficient joint review by both FDA and FSIS of petitions for approval to use a food ingredient or source of radiation in or on meat or poultry products. Applicants petitioning for approval for the use of substances in meat and poultry products provide four copies of the petition to FDA. We then forward a copy of the petition or relevant portions of the petition to FSIS so that both agencies can perform the necessary reviews simultaneously, thus reducing the time it takes to authorize an ingredient for use in meat and poultry products.

5. Impact on Small Businesses or Other Small Entities

We are unaware of ways to minimize the burdens on a small business wishing to petition for a new food or color additive or a new use of a regulated food or color additive. The agency has established criteria for the type of data necessary to demonstrate the safety of a food or color additive. Where possible, assistance is given (in fact, a significant percentage of agency time is spent in assistance activities), but we do not have the resources to conduct a firm's analytical studies or the animal feeding studies necessary to demonstrate the safety of a new additive. The labeling requirements for a specific food additive or color additive are the same regardless of the size of the firm. However, to reduce the burden on all businesses, we provide assistance to requestors to minimize the likelihood that unnecessary work is performed. We aid small businesses in complying with the petition process and labeling requirements through the agency's Regional Small Business Representatives and through the administrative and scientific staffs within the agency. We also provide assistance via our Small Business Assistance webpage at <https://www.fda.gov/industry/small-business-assistance>.

We estimate that no small businesses are involved in this information collection.

6. Consequences of Collecting the Information Less Frequently

Data collection occurs occasionally. If the collection is not conducted or is conducted less frequently, manufacturers would not be in compliance with §§ 409(a), 201(s) and 721 of the FD&C Act. Without FDA review and approval of food and color additive petitions as required by law, it would not be possible to protect the nation's food supply.

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

FDA's regulations at 21 CFR 71.1 and 171.1 require a firm to submit four copies of its petition when the firm states that the substance is intended for use in the production of meat and poultry products. We then forward the fourth copy of the petition or relevant portions of the petition to FSIS so that both agencies can perform the necessary reviews simultaneously, thus reducing the time it takes to authorize an ingredient for use in meat and poultry products. OMB previously approved this fourth copy when the regulations were amended.

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 1, 2023 (88 FR 6757.) We received 1 comment that was not PRA-related and will not be addressed in this document.

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

Food additive and color additive petitions often contain trade secret and commercial confidential information. Confidential commercial information is protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), by section 301(j) of the FD&C Act, and by part 20 of the agency's regulations (21 CFR part 20). Thus, we make no assurance of confidentiality regarding information contained in these petitions.

Privacy Act

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

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 Form FDA 3503 (Food and Color Additive Petition and Food and Color Master File) is point of contact name, business mailing address, business phone number, business fax number, and business email. FDA determined that although PII is collected, the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, the contractor or FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate form and webpage design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

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)). 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.

11. Justification for Sensitive Questions

There are no questions of a sensitive nature in the data requirements for food additive or color additive petitions.

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 Burden¹

| Activity/21 CFR Section/Form # | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Average Burden per Response | Total Hours | Total Operating and Maintenance Costs |
|---|--------------------|---------------------------------|------------------------|-----------------------------|-------------|---------------------------------------|
| Submission of Petitions: Color Additive Including Labeling--70.25, 71.1 | 2 | 1 | 2 | 1,337 | 2,674 | \$5,600 |
| Submission of Petitions: Food Additive Including Labeling--171.1 | 3 | 1 | 3 | 7,093 | 21,279 | 0 |
| Form FDA 3503 ² | 5 | 1 | 5 | 1 | 5 | 0 |
| Total | | | | | 23,958 | \$5,600 |

¹There are no capital costs associated with this collection of information.

²Form FDA 3503 is used for both CAPs and FAPs.

We have adjusted our burden estimate, which has resulted in a decrease to the currently approved burden by 1 hour. We estimate that 1 less Form FDA 3503 will be submitted to FDA creating the reduction in the burden estimate. Our estimate of burden attributable to food additive or color additive petitions is based on our experience with the information collection, which has not changed since our last review. This estimate reflects the average number of petitions we have received annually over a period of 10 years. The attendant burden we estimate also reflects an industry average, although burden associated with individual petitions may vary depending on the complexity of the petition, and the amount and type of data needed for scientific analysis.

The labeling requirements for food and color additives were designed to specify the minimum information needed for labeling in order that food and color manufacturers may comply with all applicable provisions of the FD&C Act and other specific labeling acts administered by FDA. Label information does not require any additional information gathering beyond what is already required to assure conformance with all specifications and limitations in any given food or color additive regulation. Label information does not have any specific recordkeeping requirements unique to preparing the label. Therefore, because labeling requirements under § 70.25 for a particular color additive involve information required as part of the CAP safety review process, the estimate for number of respondents is the same for §§ 70.25 and 71.1, and the burden hours for labeling are included in the estimate for § 71.1. Also, because labeling requirements under parts 172, 173, 179, and 180 for particular food additives involve information required as part of the FAP safety review process under § 171.1, the burden hours for labeling are included in the estimate for § 171.1.

12b. Annualized Cost Burden Estimate

We estimate that the average hourly wage for respondents is equivalent to a GS-14, step 4 level in the locality pay area of Washington-Baltimore in 2023, approximately \$69.77/hour. Doubling this wage to account for overhead costs, we estimate the average hourly cost to

respondents to be \$139.54/hour. The overall estimated cost incurred by the respondents is \$3,343,099.32 (23,958 burden hours x \$139.54/hour).

Table 2.--Estimated Annual Reporting Cost Burden

| Type of Respondent | Total Burden Hours | Hourly Wage Rate | Total Respondent Costs |
|---|--------------------|------------------|------------------------|
| Manufacturers or sellers of food, food ingredients, color additives, or substances used in materials that come into contact with food | 23,958 | \$139.54 | \$3,343,099.32 |

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

Color additive petitions are subject to fees. The listing fee for a CAP ranges from \$1,600 to \$3,000, depending on the intended use of the color additive and the scope of the requested amendment. A complete schedule of fees is set forth in 21 CFR 70.19. An average of one Category A and one Category B CAP is expected per year. The maximum CAP fee for a Category A petition is \$2,600, and the maximum CAP fee for a Category B petition is \$3,000. Because an average of two CAPs are expected per calendar year, the estimated total annual cost burden to petitioners for this start-up cost would be less than or equal to \$5,600 ((1 × \$2,600) + (1 × \$3,000) listing fees).

14. Annualized Cost to the Federal Government

We estimate an allocation of 5 full-time employees (FTE) annually for the review of petitions received under this information collection. The annualized cost to the Federal Government of processing petitions is calculated by multiplying FTEs used in processing petitions by the dollar value per supported position. FDA consumer safety officers review submitted petitions with input from technical reviewers. The dollar estimate for FDA consumer safety officer salary corresponds roughly to a GS-13, step 6 level in the locality pay area of Washington-Baltimore in 2023, which is \$130,683 annually. Doubling this amount to account for overhead costs, we estimate an average cost of \$261,366 per fully supported position. Thus, the total cost to the Federal Government is estimated to be around \$1,306,830 (5 FTEs x \$261,366).

15. Explanation for Program Changes or Adjustments

We have adjusted our burden estimate, which has resulted in a decrease to the currently approved burden by 1 hour. We estimate that 1 less Form FDA 3503 will be submitted to FDA creating the reduction in the burden estimate.

16. Plans for Tabulation and Publication and Project Time Schedule

We publish a notice in the *Federal Register* when a food additive or color additive petition is filed (21 CFR 71.2 or 171.1) or when a food additive or color additive regulation has been promulgated (21 CFR 71.20 or 171.100). Otherwise, the agency has no plans for publication of information from this information collection.

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

There are no reasons why display of the OMB expiration date would be inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.