Submission of Petitions: Food Additive, Color Additive (Including Labeling), and Generally Recognized as Safe Affirmation; Submission of Information to a Master File in Support of Petitions; Electronic Submission Using Food and Drug Administration Forms 3503

OMB Control No. 0910-0016

SUPPORTING STATEMENT

Terms of Clearance: None.

A. **Justification**

1. Circumstances Making the Collection of Information Necessary

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.

Generally Recognized as Safe Affirmation Petitions

Under section 201(s) of the FD&C Act, a substance is generally recognized as safe (GRAS) if it is generally recognized among experts qualified by scientific training and experience to evaluate its safety, to be safe through either scientific procedures or common use in food. The FD&C Act historically has been interpreted to permit food manufacturers to make their own initial determination that use of a substance in food is GRAS and thereafter seek affirmation of GRAS status from FDA. FDA reviews petitions for affirmation of GRAS status that are submitted on a voluntary basis by the food industry and other interested parties under authority of sections 201, 402, 409, and 701 of the FD&C Act (21 U.S.C. 321, 342, 348, and 371). To implement the GRAS provisions of the FD&C Act, FDA has set forth procedures for the GRAS affirmation petition process in § 170.35(c)(1) of its regulations (21 CFR 170.35(c)(1)). While the GRAS affirmation petition process still exists, FDA has not received a GRAS affirmation petition since the establishment of the voluntary GRAS notification program and is not expecting any during the period covered by this proposed extension of collection of information.

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 the agency's 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, 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 food or color master files (master files) 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. FDA estimates that the amount of time for respondents to complete FDA Form 3503 will continue to be 1 hour.

FDA requests extension of OMB approval of the information collection requirements in the following citations: 21 CFR 70.25, 71.1, 170.35, 171.1, 172, 173, 179, and 180, 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, cosmetics, or medical devices. FDA personnel also review GRAS affirmation petitions to evaluate safety.

Description of Respondents: Respondents are typically 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

FDA has an option for electronic submission via the Electronic Submission Gateway (ESG) for this information collection. The ESG is an electronic system that also accepts information for other information collections. Respondents may transmit FAP or CAP regulatory submissions in electronic format via the ESG 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.

FDA estimates that 50% of the respondents will electronically submit the information being collected via the ESG or on a physical media (e.g., CD-ROM or DVD).

4. Efforts to Identify Duplication and Use of Similar Information

FDA continues 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 FDA enforces 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 21 CFR 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. FDA then forwards 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

There is no known way to minimize the burdens on a small business wishing to petition for a new food or color additive or GRAS ingredient or a new use of a regulated food or color additive or GRAS ingredient. 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 FDA does 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, FDA provides assistance to requestors to minimize the likelihood that unnecessary work is performed. FDA aids 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. FDA has provided a Small Business Guide on the agency's website at http://www.fda.gov/oc/industry/.

FDA estimates 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 additive, color additive, and GRAS affirmation

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. . FDA then forwards 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), in the Federal Register of April 16, 2014 (79 FR 21469), FDA published a 60-day notice requesting public comment on the information collection provisions. FDA received 1 letter containing multiple comments. This letter was not addressed in the agency's 30-day notice as the comment was not posted to the docket until after close of the comment period. We do, however, address the comment here.

(Comment 1) One comment supports this information collection. The comment stated that information submitted in an organized manner would assist FDA with future petitions and inquiries and information of practical utility can be beneficial to the agency.

(Response) FDA agrees. The information collection allows data to be submitted in an organized manner to facilitate FDA review of FAPs, CAPs, and GRAS affirmation petitions, in support of ensuring the safety of the nation's food supply. Information can also be placed into master files, which 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.

(Comment 2) One comment states that it is unclear whether the burden estimate reflects past or current petitions. It adds that if any processes for the review of FAPs or GRAS petitions change, then so will the number of submissions to the agency.

(Response) The burden estimate reflects FDA's estimate of the burden on the public for the next 3 years to comply with this information collection. FDA bases its estimate on its experience and the number of petitions received in the past 3 years. If the number of petitions submitted to FDA were to change, FDA would adjust its estimate when submitting its request for renewal to OMB, which occurs approximately every 3 years.

(Comment 3) One comment agrees that the current list of information available to the agency is sufficient.

(Response) It is unclear to FDA what "current list of information available to the agency" to which the comment is referring.

(Comment 4) One comment suggests that the automated system to collect information may create an unnecessary burden on industry. The comment states that many manufacturers must contract

third parties for submissions because the system is complex and time consuming. Further, the comment states that some users had difficulty installing the software needed to use the automated system.

(Response) The ESG is a central transmission point for sending information electronically. ESG routes the submission to the appropriate FDA program office. Form FDA 3503 is completed electronically and then uploaded to ESG. The ESG allows FDA to process submissions in a more efficient manner. The software needed to use ESG includes a web browser and Java. FDA has provided a user guide and other helpful information on its webpage at http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm. FDA also provides, on the webpage, contact information to submit questions regarding registration and technical issues. Respondents may also transmit FAP or CAP regulatory submissions in electronic format on physical media or in paper format. GRAS affirmation petitions may be submitted to FDA in paper format as well.

(Comment 5) One comment suggests that data security should be a priority for automated systems because of the sensitive information being submitted.

(Response) FDA agrees. The overall purpose of the ESG is to provide a centralized, agency-wide communications point, and it enables the secure electronic submission of regulatory information to FDA for review. The ESG uses a software application certified to comply with secure messaging standards.

9. Explanation of Any Payment or Gift to Respondents

FDA does not provide any payment or gift to respondents.

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). In contrast, all information contained in a GRAS affirmation petition is made available for public disclosure pursuant to § 170.35(c)(2). Thus, FDA makes no assurance of confidentiality regarding information contained in these petitions.

11. Justification for Sensitive Questions

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

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

Description of Respondents: Respondents are typically 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)..

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

21 CFR Section/FDA Form	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours	Total Operating and Maintenance Costs
Color Additive Petitions						
70.25, 71.1	2	1	2	1,337	2,674	$5,600
GRAS Affirmation Petitions						
170.35	1 or fewer	1	1 or fewer	2,614	2,614	0
Food Additive Petitions						
171.1	3	1	3	7,093	21,279	0
FDA Form 3503	6	1	6	1	6	0
Total					26,573	$5,600

Table 1.--Estimated Annual Reporting Burden

The estimate of burden for food additive, color additive, or GRAS affirmation petitions is based on FDA's experience with the petition process. FDA is retaining its prior estimate of the number of petitions received because the average number of petitions received annually has varied little over the past 10 years. The figures for hours per response are based on estimates from experienced persons in the agency and in industry. Although the estimated hour burden varies with the type of petition submitted, an average petition involves analytical work and appropriate toxicological studies, as well as the work of drafting the petition itself. The burden varies depending on the complexity of the petition, including the amount and types of data needed for scientific analysis.

Color additives are subjected to payment of fees for the petitioning process. The listing fee for a color additive petition 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 § 70.19. An average of one Category A and one Category B color additive petition is expected per year. The maximum color additive petition fee for a Category A petition is $2,600 and the maximum color additive petition fee for a Category B petition is $3,000. Because an average of 2 color additive petitions 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 = $5,600). There are no capital costs associated with color additive petitions.

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.

12 b. Annualized Cost Burden Estimate

FDA estimates 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 2014, approximately $56/hour. Doubling this wage to account for overhead costs, FDA estimates the average hourly cost to respondents to be $112/hour. The overall estimated cost incurred by the respondents is $2,976,176 (26,573 burden hours x $112/hr = $2,976,176).

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

Color additives are subject to payment of fees for the petitioning process. The listing fee for a color additive petition 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 color additive petition is expected per year. The maximum color additive petition fee for a Category A petition is $2,600 and the maximum color additive petition fee for a Category B petition is $3,000. Since an average of two color additive petitions 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 x $2,600) + (1 x $3,000) listing fees = $5,600).

14. Annualized Cost to the Federal Government

FDA estimates that the review of petitions received under this information collection accounts for 4.9 person years (PY) of professional time annually. The annualized cost to the Federal government of processing petitions is derived by multiplying the person-year 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 wages corresponds roughly to a GS-13, step 6 level in the locality pay area of Washington-Baltimore in 2014, which is $104,911 annually. Doubling this amount to account for overhead costs, FDA estimates an average cost of $209,822 per fully supported position. Thus, the total cost to the Federal government is estimated at $1,028,127.80 (4.9 PY x $209,822/PY).

15. Explanation for Program Changes or Adjustments

The burden estimate is unchanged.

16. Plans for Tabulation and Publication and Project Time Schedule

FDA publishes a notice in the Federal Register when a food additive or color additive petition is filed (21 CFR 71.2 or 171.1); when a food additive or color additive regulation has been promulgated (21 CFR 71.20 or 171.100); and, when a GRAS affirmation petition is filed (21 CFR 170.35(c)(2)). 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 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.