Submission of Petitions: Food Additive, Color Additive (Including Labeling), and Generally Recognized as Safe Affirmation; Electronic Submission Using Food and Drug Administration Forms 3503 and 3504

OMB Control No. 0910-0016

SUPPORTING STATEMENT

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 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 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 act is effective. Food additive petitions 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 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 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 act (21 U.S.C. 321, 342, 348, and 371). To implement the GRAS provisions of the 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)).

In the Federal Register of April 17, 1997 (62 FR 18938) FDA proposed to replace the current GRAS affirmation process with a notification procedure whereby any person may notify FDA of their determination that a particular use of a substance is GRAS. The format for a GRAS notice is spelled out in the 1997 proposed rule. The notifier would receive only a letter from FDA. FDA has been accepting GRAS notices under this proposed rule, which is approved under OMB control number 0910-0342. . 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 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 act. Color additive petitions 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

Currently, interested persons may transmit regulatory submissions to the Office of Food Additive Safety in the Center for Food Safety and Applied Nutrition using Form FDA 3503 for food additive petitions and Form FDA 3504 for color additive petitions. FDA is revising Form FDA 3503 to better enable its use for electronic submission and to permit its use for multiple types of submissions, which eliminates the need for Form FDA 3504. Because Form FDA 3503 helps the respondent organize their submission to focus on the information needed for FDA's safety review, FDA now recommends that this form be used for food additive petitions and color additive petitions, whether submitted in electronic format or paper format. FDA estimates that the amount of time for respondents to complete the revised FDA Form 3503 will continue to be 1 hour. The revised Form FDA 3503 can be used to submit information to FDA in electronic format using the Electronic Submission Gateway portal. The revised Form FDA 3503 can be used to substitute for the "Dear Sir" section of 21 CFR 71.1(c) for a color additive petition and 21 CFR 171.1 (c) for a food additive petition. The revised Form FDA 3503 provides for submitters to indicate the date of their most recent presubmission consultation activity with FDA. The revised 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. The revised Form FDA 3503 is formatted to accept submissions for both food additive petitions and color additive petitions, thus making redundant Form FDA 3504 for collecting color additive petition submissions. Therefore, FDA is eliminating Form FDA 3504.

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 food additive petitions to ensure the safety of the intended use of

the additive in or on food. Likewise, FDA personnel review color additive petitions 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 to this information collection are persons or businesses petitioning for FDA approval of a new food additive, color additive, or GRAS ingredient or a new use of a regulated food additive, color additive, or GRAS ingredient. Respondents are from the private sector (for-profit businesses).

3. Use of Improved Information Technology and Burden Reduction

FDA is not equipped to receive these submissions solely by electronic means at this time. Instead, FDA permits respondents to submit a food additive petition or color additive petition electronically when accompanied by a signed FDA Form 3503. FDA is working diligently to develop the necessary technology infrastructure to enable it to accept these submissions electronically in the future. The agency has made progress toward completion of a Public Key Infrastructure (PKI) capable system that we expect to enable us to accept these submissions electronically. Accordingly, FDA has carefully evaluated the nature and regulatory significance of the submission, in particular the significant legal consequences attendant to the signing and submitting of the petition. FDA requests that the agency be authorized to continue this information collection activity in non-electronic format.

The petition must be signed by a responsible person, and in signing the petition, that person is certifying that the information is accurate and that the firm is in possession of substantiation that the subject of the petition is truthful and not misleading. The signatory of the petition is, therefore, assuming potential liability under 18 U.S.C. 1001. Moreover, if the person who signs the petition is, in fact, not a responsible person authorized by the firm to certify that the firm is in compliance with all applicable requirements of the act, then the submission of a noncompliant petition may also exposure the firm and/or its products to liability under the act.

The petition carries legal implications for the firm and the signatory. Therefore, these documents carry significant risk of repudiation. For this reason, FDA believes that the significant legal consequences attendant to the signature warrant a level of authentication and signer non-repudiation that only digital signatures in a PKI model can currently provide. Because CFSAN lacks that model, but is working with other FDA units toward putting it in place, the agency believes that other forms of electronic submission that the agency might be able to accept present unacceptable risks that provide a basis to not accept these submissions electronically until an acceptable infrastructure is in place.

FDA estimates that 50% of the respondents will electronically submit the information being collected.

4. Efforts to Identify Duplication and Use of Similar Information

FDA continues to work with EPA and 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 do 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 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 the substance is intended for use in the production of meat and poultry products, to permit a joint review of the petition by both FDA and the Food Safety and Inspection Service (FSIS), U.S. Department of Agriculture (USDA). 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. 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 June 14, 2010 (75 FR 33624), FDA published a 60-day notice requesting public comment on the information collection provisions. FDA received no comments.

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 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 to this information collection are persons or businesses petitioning for FDA approval of a new food additive, color additive, or GRAS ingredient or a new use of a regulated food additive, color additive, or GRAS ingredient.

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

21 CFR Section/FDA Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Operating and Maintenance Costs	Total Hours
Color Additive Petitions						
70.25, 71.1	2	1	2	1,337	$5,600	2,674
GRAS Affirmation Petitions						
170.35	1 or fewer	1	1 or fewer	2,614	0	2,614
Food Additive Petitions						

171.1	3	1	3	7,093	0	21,279
FDA Form 3503	6	1	6	1	0	6
Total					$5,600	26,573

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 and the average number of new petitions received in calendar years 2006, 2007, 2008, and 2009, and the total hours expended in preparing the petitions. In compiling these estimates, FDA consulted its records of the number of petitions received in the past four 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.

FDA identifies three tiers of color additive petitions that represent escalating levels of burden required to collect information, denoted as Categories A, B, and C. Category A: A typical medical device color additive petition with minimal testing requirements (toxicity studies, collection of identity information, analytical information, and administrative details) requires approximately 675 hours per petition. Category B: An average color additive petition consisting of analytical work, 90-day feeding study, and the administrative details, which include the drafting of the regulations, requires approximately 2660 hours per petition. Category C: A petition for a completely new food, drug, and cosmetic color. No petitions of this kind were received in calendar years 2006-2009, so we are not including this potential burden at this time. On average, FDA estimates the reporting burden for Category A and B petitions to be 1,337 hours per response. FDA estimates that two respondents will submit one color additive petition annually, for a total of two responses. Thus, table 1 above reports an estimated total of 2,674 burden hours associated with color additive petitions filed under 21 CFR 70.25 and 71.1 (2 petitions x 1,337 hours per petition).

In the last 3 years, FDA has not received any new GRAS affirmation petitions. Although FDA has not received any new GRAS affirmation petitions in the last 3 years, it believes these information collection provisions should be extended to provide for the potential future need of businesses. Therefore, the agency estimates that one or fewer petitions will be submitted annually. FDA estimates the reporting burden for GRAS affirmation petitions to be 2,614 hours per response. Thus, table 1 above reports an estimated total of 2,614 burden hours associated with GRAS affirmation petitions filed under 21 CFR 170.35 (1 petitions x 2,614 hours per petition).

Since 1980, FDA has not received any petitions for affirmation of GRAS status under 21 CFR part 186--Indirect Food Substances Affirmed As Generally Recognized As Safe. Furthermore, 21 CFR 184.1(a) affirms the use of those substances affirmed as GRAS in 21 CFR part 184--Direct Food Substances Affirmed As Generally Recognized As Safe, for use as indirect food ingredients.

FDA identifies three tiers of food additive petitions that represent escalating levels of burden required to collect information, denoted as Categories 3, 4, and 5. (The burden of Categories 1 and 2 are reported in the collection of information titled, "Food Additives; Food Contact Substances Notification System," approved under OMB control number 0910-0495. The following three

categories of types of petitions represent information collection and burden estimates for food additive petitions submitted to amend 21 CFR parts 172, 173, 179, and 180. Category 3: The simplest petition for a direct food additive involves a request for a technical change in the regulation for a previously regulated substance. A technical change requires approximately 160 hours per petition, including simple analytical work and administrative details. No toxicological studies are required. Category 4: Most petitions for direct food additives are for new uses of previously regulated substances. An average direct additive petition, including toxicological studies, analytical work, and administrative details, requires approximately 3,600 hours. Category 5: A petition for a previously unregulated direct food additive, that requires long-term toxicological studies, analytical work, and administrative details, would require approximately 28,000 hours per petition. On average, FDA estimates the reporting burden for Category 3, 4 and 5 petitions to be 7,093 hours per response. FDA estimates that three respondents will submit one food additive petition annually, for a total of three responses. Thus, table 1 above reports an estimated total of 21,279 burden hours associated with food additive petitions filed under 21 CFR 171.1 (3 petitions x 7,093 hours per petition).

FDA estimates that each of the 6 respondents described above will prepare a Form FDA 3503. We estimate that petitioners will only need to spend approximately 1 hour completing Form FDA 3503 because they will have already prepared and organized the petition information needed for the submission. Thus, table 1 above reports an estimated total of 6 burden hours associated with Form FDA 3503 (6 responses x 1 hour per petition).

The labeling requirements for food additives 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 Food, Drug, and Cosmetic 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 21 CFR 70.25 for a particular color additive involve information required as part of the color additive petition safety review process, the estimate for number of respondents is the same for 21 CFR 70.25 and 71.1, and the burden hours for labeling are included in the estimate for 21 CFR 71.1. Also, because labeling requirements under 21 CFR parts 172, 173, 179, and 180 for particular food additives involve information required as part of the food additive petition safety review process under 21 CFR 171.1, the burden hours for labeling are included in the estimate for 21 CFR 171.1.

12 b. Annualized Cost Burden Estimate

FDA estimates that the average hourly wage for respondents is equivalent to a GS-14-4 level in the locality pay area of Washington-Baltimore in 2010, 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 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 GS level 13, step 6, which is $95,459 annually per the 2010 GS Salary Table. Doubling this wage to account for overhead costs, FDA estimates an average cost of $190,918 per fully supported position. Thus, the total cost to the Federal government is estimated at $935,498.20 (4.9 PY x $190,918/PY).

15. Explanation for Program Changes or Adjustments

The changes to Form FDA 3503 and elimination of Form FDA 3504 may be characterized as a "revision" or "program change." This revision is a consolidation of forms . Further, the revised form FDA 3503 can be used as described (page 2), to submit information to FDA in electronic format using the Electronic Submission Gateway and is formatted to accept submissions for both food additive petitions and color additive petitions, thus making redundant Form FDA 3504 for collecting color additive petition submissions. Therefore, FDA is discontinuing Form FDA 3504. and as a result of this revision,

The decrease in burden may be characterized as an adjustment and is due to the decrease in the estimated number of respondents for food additive petitions, i.e. from three to two.

Costs have decreased since the previous approval. FDA is estimating total start-up cost of $5,600, (refer to item 13). The decrease of $2,600 reflects one fewer category "A" color additive petition expected to be submitted.

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.