SUPPORTING STATEMENT

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 No. 0910-0016

A. JUSTIFICATION

1. Need and Legal Basis

Food Additive Petitions and Labeling Requirements

Section 409(a) of the Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C. § 348) provides that a food additive shall be deemed to be unsafe unless: 1) it and its use or intended use are in conformity with a regulation prescribing the condition(s) under which such additive may safely be used; 2) it and its use or intended use conform to the terms of a regulatory exemption for investigational use; or 3) for a food contact substance, the substance and the use of such substance are in conformity with a regulation prescribing the conditions under which such additive may be safely used or a food contact notification submitted under subsection (h) is effective. With the exception of notifications for food additives that are food contact substances, food additive petitions provide the only method for premarket safety review and approval of food additives permitted by law. Section 409(b) of the act specifies the information that must be submitted by a petitioner to establish the conditions under which a food additive may be safely used.

FDA's regulations in Title 21 of the Code of Federal Regulations, part 171 (21 CFR part 171) specify the information that must be submitted in a food additive petition to meet the statutory requirements. The regulations also provide a standard format to expedite processing of the petition.

Labeling requirements for food additives intended for human consumption, addressing information needed by a manufacturer to use the additive safely, are set forth in various regulations contained in 21 CFR parts 172, 173 and 180. Labeling requirements for indirect food additives are set forth in several individual regulations contained in 21 CFR parts 175 through 178. The labeling regulations are considered by FDA to be cross referenced to § 171.1.

Generally Recognized as Safe Affirmation Petitions

Section 201(s) of the act (21 U.S.C. § 321(s)) defines a generally recognized as safe (GRAS) substance as an exception from the legal definition of a food additive. This section defines a substance as 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 under the conditions of its intended use. Section 201(s) of the act does not define what is meant by "scientific procedures" or "common use in food," nor does it specify how the

substance is to be evaluated as GRAS. To implement the GRAS provisions of § 201(s), FDA has issued procedural regulations in 21 CFR part 170. The procedural regulations at 21 CFR 170.30 are designed to delineate and specify, with particularity, eligibility for classification as GRAS, and to set forth the information that must be submitted to FDA to gain agency concurrence that a substance is GRAS. The regulations add no substantive requirements to the law, but attempt to explain the requirements for classification as GRAS. More specifically, the procedural regulations in 21 CFR 170.35(c)(1) provide a standard format for submission of GRAS affirmation petitions.

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. Since there have been no GRAS affirmation petitions received since the 1997 proposed rule, FDA is assigning minimal burden to the information collection requirements in 21 CFR 170.35.

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: 1) unless the additive and its use are in conformity with a regulation listing such additive for such use, including any provision that describes the condition(s) under which the additive may safely be used and is either batch certified for such use or exempted from the certification requirements, or 2) unless the additive and its use conform to the terms of an exemption for investigational use. Section 721(b) of the act (21 U.S.C. § 379e(b)) specifies the information that must be submitted by a petitioner in order to establish that a color additive is safe and suitable for its proposed use. FDA's regulations in 21 CFR part 71 specify the information that must be submitted in a color additive petition to meet the statutory requirements. The regulations also provide a standard format to expedite processing of the petition.

The labeling requirements for color additives intended for foods, drugs, devices, or cosmetics are set forth in FDA's regulations in 21 CFR parts 73 and 74. These labeling requirements cross reference to 21 CFR 70.25, which requires that color additives to be used in foods, drugs, devices, or cosmetics be labeled with sufficient information to ensure their safe use.

Electronic Submission Using FDA Forms 3503 and 3504

FDA is in the process of finalizing a draft guidance document entitled, "Draft Guidance for Industry: Providing Regulatory Submissions in Electronic Format for Food Additive and Color Additive Petitions,"(available at http://www.cfsan.fda.gov/guidance.html). Attached as appendixes to this draft guidance are FDA Form 3503, entitled "Food Additive Petition Submission Application" and FDA Form 3504, entitled "Color Additive Petition Submission Application," and their instructions. The information to be collected using Form 3503 or 3504 is the same information that is currently collected in petitions submitted as paper records. FDA believes that use of these forms will facilitate both the preparation and review of food and color

additive petitions because they organize the information necessary to support the safety of the use of food and color additives. FDA also expects that use of the forms will decrease the overall paperwork burden on respondents.

This guidance did not specifically address GRAS affirmation petitions because FDA does not expect to receive any further GRAS petitions. As noted above, GRAS submissions are now received in the form of a GRAS notice, approved under OMB No. 0910-0342. However, a GRAS affirmation petition could be submitted electronically using the same guidance as that for a food additive petition.

FDA requests extension of OMB's approval of the information collection requirements in the following citations and forms: 21 CFR 70.25, 71.1, 170.35, 170.1, 172, 173, 179, 180 and FDA Forms 3503 and 3504.

2. Information Users

A person or business wishing to request FDA approval to use a new food or color additive or GRAS ingredient, or a new use of a regulated food or color additive or GRAS ingredient, submits the required information to FDA in a petition. FDA uses the information in the petition to determine whether the request meets the criteria for food safety required by statute and regulation.

3. Improved Information Technology

FDA is not equipped to receive these submissions solely by electronic means at this time. Instead, FDA has issued the draft guidance discussed above, which permits respondents to submit a food additive petition or color additive petition electronically when accompanied by a signed FDA Form 3503 or 3504. 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.

4. Duplication 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. Small Businesses

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 dealing with the submission requirements through the Division of Education and Communication in the Center for Food Safety and Applied Nutrition (CFSAN) and through the scientific and administrative staffs of the agency.

6. Less Frequent Collection

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

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. *Federal Register* Notice/Outside Consultation

In accordance with 5 CFR 1320.8(d), in the Federal Register of January 19, 2007 (72 FR 2533), FDA published a 60-day notice requesting public comment on the information collection provisions. FDA received no comments responsive to the comment request.

9. Payment/Gift to Respondent

This information collection does not provide for any payment or gift to respondents.

10. Confidentiality

Food additive and color additive petitions often contain trade secret and commercial confidential information. Only information that is releasable under 21 CFR part 20 would be released to the public. This information is also safeguarded by Section 301(j) of the 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)). 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. Sensitive Questions

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

12. Burden Estimate (Total Hours and Wages)

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
CAPs						
70.25,71.1	3	1	3	1,337 1336.6666	$8,200	4,010
FDA Form 3504	1	1	1	1	0	1
GRAS Affirmation Petitions						
170.35	1 or fewer	1	1 or fewer	2,614	0	2,614
FAPs						
171.1	6	3	6	7,093 7093.3333	0	42,560
FDA Form 3503	1	1	1	1	0	1
Total					$8,200	49,186

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

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

The estimate of burden for food additive and color additive petitions is based on FDA's experience and the average number of new food additive and color additive petitions received in calendar years 2003-2005 and the total hours expended in preparing the petitions. In compiling these estimates, FDA consulted its records of the number of petitions received. The figures for hours per response are based on estimates from experienced persons in the agency and in industry. Although the burden varies with the type of petition submitted, an average food additive, color additive, or GRAS affirmation 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.

The burden to respondents is similar between the preparation of petitions submitted to amend 21 CFR parts 175 through 178 and the preparation of a food contact substance notification. FDA transferred the collection of information and burden associated with petitions submitted to amend the indirect food additive regulations (21 CFR parts 175 through 178) from this collection of information (OMB control number 0910-0016) to the existing collection of

information for the Food Contact Substances Notification System (OMB control number 0910-0495).

The following two categories of types of petitions represent estimates of information collection burden for food additive petitions submitted to amend the indirect food additive regulations (21 CFR parts 175 through 178). The burden was transferred to the existing collection of information for the Food Contact Substances Notification System (OMB control number 0910-0495). These two petition types may be eligible for exemption as food contact substances, subject to exemption as food contact substances.

Category 1. For an indirect additive petition with complex analytical problems, the estimated time requirement per petition is approximately 3990 hours. One petition of this type was received between 2003 and 2005, resulting in a burden of 3990 hours. We are transferring this burden to the existing collection of information for the Food Contact Substances Notification System (OMB control number 0910-0495).

Category 2. A petition for a major new polymer for food packaging, involving long-term feeding studies, toxicology review, analytical work, and administrative details, requires approximately 18,000 hours. Although no such petitions have been received in recent years, we are transferring the potential burden of one or fewer petitions to the existing collection of information for the Food Contact Substances Notification System (OMB control number 0910-0495), resulting in a burden of 18,000 hours.

FDA estimates the annual reporting burden associated with petitions submitted to amend parts 175 through 178 to be transferred from OMB control number 0910-0016 to OMB control number 0910-0495. An average of two indirect food additive petitions are expected per calendar year. The estimated total annual hour burden to petitioners is a total of 21,990 hours ((1 x 3990 hours) + (1 x 18,000 hours)). There are no capital costs or operating and maintenance costs associated with the burden hours being transferred from OMB control number 0910-0016 to OMB control number 0910-0945.

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. One petition of this type was received during 2003-2005, resulting in a burden of 160 hours.

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. An average of four petitions of

this type were received on an annual basis between 2003 and 2005, resulting in a burden of 14,400 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. One petition of this type was received between 2003-2005, resulting in a burden of 28,000 hours.

Thus, table 1 above reports an estimated total of 42,560 burden hours associated with food additive petitions filed under 21 CFR 171.1 (160 hours + 14,400 hours + 28,000 hours).

The following category examples represent estimates of information collection burden for color additive petitions.

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. An average of two petitions of this type were received on an annual basis between 2003 and 2005, resulting in a burden of 1350 hours.

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. An average of one petition of this type was received on an annual basis between 2003 and 2005, resulting in an annual burden of 2660 hours.

Category C. A petition for a completely new food, drug, and cosmetic color. No petitions of this kind were received in calendar years 2003-2005, so we are not including this potential burden at this time.

Thus, table 1 above reports an estimated total of 4,010 burden hours associated with food additive petitions filed under 21 CFR 70.25 and 71.1 (1,350 hours + 2,660 hours).

FDA estimates that it may receive one or fewer GRAS petition annually. The agency estimates the average information collection burden for a GRAS affirmation petition to be 2614 hours, as reported in table 1.

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.

Electronic submissions of petitions contain the same petition information required for paper submission. The agency estimates that one petitioner for both a food additive and color additive will take advantage of the electronic submission process per year. By using the guidelines and

forms that FDA is providing, the petitioner will be able to organize the petition to focus on the information needed for FDA's safety review. Therefore, we estimate that petitioners will only need to spend approximately 1 hour completing the electronic submission application form (form 3503 or 3504, as appropriate) because they will have already used the guidelines to organize the petition information needed for the submission.

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 under 21 CFR 70.25 labeling requirements 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 FAP safety review process under 21 CFR 171.1, the burden hours for labeling are included in the estimate for 21 CFR 171.1. In cases where a regulation implements a statutory information collection requirement, only the additional burden attributable to the regulation, if any, has been included in FDA's burden estimate.

Costs to Respondents. FDA estimates that there has been a 17 percent increase in the technical occupation hourly wage since the last estimate of $48 per hour, and thus the current hourly wage is estimated to be approximately $56 (1.17 x $48=$56.16). Doubling this wage to account for overhead costs, FDA estimates the hourly cost to respondents to be $112. The overall estimated cost incurred by the respondents is $5,508,832 (49,186 burden hours X $112/hr = $5,508,832).

13. Capital Costs (Maintenance of Capital Costs)

There are no fees required for the submission of food additive or GRAS affirmation petitions, and there are no capital or start up costs to respondents.

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 two Category A and one Category B color additive petitions are 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 three 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 $8,200 ((2 x $2,600) + (1 x $3,000) listing fees = $8,200). There are no capital costs associated with color additive

petitions.

14. Cost to Federal Government

FDA estimates that the review of petitions received under this information collection accounts for 4.9 person years 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. Thus, based on an average cost of $119,000 per fully supported position, the cost of processing food additive and color additive petitions is $583,100 per year (4.9 PY x $119,000/PY = $583,100).

15. Program or Burden Changes

The increase in burden is primarily due to the increase in the estimated hours per response for food additive petitions.

The change in cost is actually an increase from the previous approval. The supporting statement requested approval of $5,600 total capital costs but the NOA incorrectly indicates $560,000. For this approval extension request, FDA is estimating a total capital cost of $8,200. The increase of $2,600 reflects one additional category A petition expected to be submitted.

16. Publication and Tabulation Dates

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. Display of OMB Approval Date

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"

N/A