

Supporting Statement for Food Additive Petitions  
(OMB Approval Number 0910-0016)

**A. Justification**

**(1) Circumstances Necessitating Information Collection**

Section 409(a) (Tab 1) of the Federal Food, Drug and Cosmetic Act (FFDCA) provides that a food additive shall be deemed to be unsafe unless its use is permitted by a regulation which prescribes the condition(s) under which it may safely be used, or unless it is exempted by regulation for investigational use, or unless a food contact notification submitted under subsection (h) is effective. Section 409(b) (Tab 1) of FFDCA specifies the information that must be submitted by a petitioner in order to establish the safety of a food additive and to secure the issuance of a regulation permitting its use.

To implement the provisions of Section 409, procedural regulations have been issued under Part 171 of 21 CFR. These procedural regulations are designed to further delineate and specify more thoroughly the information that must be submitted to meet the requirements set down in broader terms by the law. The regulations add no substantive requirements to those indicated in the law, but attempt to explain the requirements more specifically and provide a standard format for submission in order to speed the processing of the petition. Labeling requirements for food additives intended for human consumption are also set forth in various regulations contained in Parts 172, 173, and 180. Labeling requirements for indirect food additives are set forth in several individual regulations contained in Parts 175-178. The labeling regulations are considered by FDA to be cross referenced to §171.1, which is the subject of this same OMB clearance for food additive petitions (0910-0016).

We are requesting the extension of the OMB approval of the information collection requirements contained in:

21 CFR 171.1 Reporting (Tab 2)

Requests specific data be provided to demonstrate safe use of food additives under proposed use and provides a format for submission of petitions.

21 CFR 172 Disclosure - Labeling (Tab 3)

Requires directions to be given for safe use of food additives intended for direct human consumption under prescribed conditions.

## 21 CFR 173 Disclosure - Labeling (Tab 4)

Requires directions to be given for the safe use of additives used in the production of food or food additives, but not added directly to food for an intended effect (secondary direct food additives).

## 21 CFR Parts 175-178 - Labeling (Tabs 5 - 8)

Requires directions to be given for safe use of indirect food additives. Specific citations requested for Parts 175-178 include:

176.160(c) - Directions for safe use of chromium complex of N-ethyl-N-heptadecylfluoro-octane sulfonoyl glycine.

176.300(b) - Directions for safe use of slimicides.

177.2250(g) - Directions for safe use of filters, microporous polymeric.

177.2910(f) - Directions for safe use of ultra-filtration membranes.

178.3520(c) - Directions for safe use of industrial starch-modified.

## 21 CFR 180 Disclosure - Labeling (Tab 9)

Requires directions to be given for safe use of food additives permitted in food on an interim basis or in contact with food pending additional study. A specific citation requested for Part 180 is 180.37(f)(1)(iii) - directions for safe use of saccharin, ammonium saccharin, calcium saccharin, and sodium saccharin.

21 CFR 172 and 173 directly cross reference Food Additive Petitions, OMB 0910-0016. Specific citations for these 2 parts follow with an explanation of each requirement.

Part 172 - Applies to food additives for direct human consumption.

172.110(c)(2,3) - Directions for safe use of the food additive BHA.

172.115(c)(2) - Directions for safe use of the food additive BHT.

172.120(c)(2) - Directions for safe use of the food additive calcium disodium EDTA.

172.130(c) - Direction for safe use of the food additive dehydroacetic acid.

172.133(c)(2) - Directions for safe use of the food additive dimethyl

dicarbonate.

172.135(c)(2) - Directions for safe use of the food additive disodium EDTA.

172.170(b)(2) - Directions for safe use of the food additive sodium nitrate.

172.175(b)(2) - Directions for safe use of the food additive sodium nitrite.

172.177(e)(2) - Directions for safe use of the food additive sodium nitrite.

172.215(d)(2) - Directions for safe use of the food additive coumarone-indene resin.

172.230(c) - Directions for safe use of microcapsules for flavoring substances.

172.320(e)(3) - Directions for safe use of the food additive amino acids.

172.372(e)(3) - Directions for safe use of the food additive N-acetyl-L-methionine.

172.385(f)(2) - Directions for safe use of the food additive whole fish protein concentrate.

172.430(c)(2) - Directions for safe use of the food additive iron ammonium citrate.

172.520 - Directions for safe use of the food additive cocoa with dioctyl sodium sulfosuccinate for manufacturing.

172.623(e) - Directions for safe use of the food additive carrageenan with polysorbate 80.

172.665(f)(2) - Directions for safe use of the food additive gellan gum.

172.695(f)(2) - Directions for safe use of the food additive xanthan gum.

172.725(c)(3,4) - Directions for safe use of the food additive gibberellic acid.

172.730(b)(2) - Directions for safe use of the food additive potassium bromate.

172.770(c) - Directions for safe use of the food additive ethylene oxide polymer.

172.802(d)(3) - Directions for safe use of the food additive acetone peroxides.

172.804(d)(3,4) - Directions for safe use of the food additive aspartame.

172.806(b)(2) - Directions for safe use of the food additive azodicarbonamide.

172.810(f) - Directions for the safe use of the food additive dioctyl sodium sulfosuccinate.

172.811(d)(2) - Directions for the safe use of the food additive glyceryl tristearate.

172.812(c)(1, 2) - Directions for the safe use of the food additive glycine.

172.814(c)(2) - Directions for the safe use of the food additive hydroxylated lecithin.

172.818(c)(2) - Directions for the safe use of the food additive oxysterin.

172.822(c)(2) - Directions for the safe use of the food additive sodium lauryl sulfate.

172.824(c)(1, 2) - Directions for the safe use of the food additive sodium mono- and dimethyl naphthalene sulfonates.

172.832(c)(2) - Directions for the safe use of the food additive monoglyceride citrate.

172.836(d)(2) - Directions for the safe use of the food additive polysorbate 60.

172.838(d)(2) - Directions for the safe use of the food additive polysorbate 65.

172.840(d)(2) - Directions for the safe use of the food additive polysorbate 80.

172.842(d)(2) - Directions for safe use of the food additive sorbitan monostearate.

172.844(d)(2) - Directions for the safe use of the food additive calcium stearoyl-2-lactylate.

172.858(c)(2) - Directions for the safe use of the food additive propylene glycol alginate.

172.874(c) - Directions for safe use of the food additive hydroxypropyl methylcellulose.

172.898(e) - Directions for safe use of the food additive bakers yeast glycan.

PART 173 - Applies to additives used in the production of food or food additives, but not added directly to food for an intended effect.

173.10(d) - Directions for the safe use of the food additive modified polyacrylamide resin.

173.25(c)(2) - Directions for the safe use of the food additive ion-exchange resins.

173.60(d) - Directions for the safe use of the food additive dimethylamine-epichlorohydrin copolymer.

173.240(c)(2) - Directions for the safe use of the food additive isopropyl alcohol.

173.250(b)(2) - Directions for the safe use of the food additive methyl alcohol residues.

173.255(b)(2) - Directions for the safe use of the food additive methylene chloride.

173.270(b)(2) - Directions for the safe use of the food additive hexane.

173.310(e)(2) - Directions for the safe use of the food additive boiler water additives.

173.315(d)(2) - Directions for the safe use of food additive chemicals used in washing or to assist in the peeling of fruits and vegetables.

173.320(c) - Directions for the safe use of food additive chemicals for controlling microorganisms in cane-sugar and beet-sugar mills.

173.345(c)(2) - Directions for the safe use of the food additive chloropentafluoroethane.

173.350(d) - Directions for the safe use of the food additive combustion product gas.

173.355(c)(2) - Directions for the safe use of the food additive dichlorodifluoromethane.

173.360(c)(2) - Directions for the safe use of the food additive octafluorocyclobutane.

173.400(d) - Directions for the safe use of the food additive dimethyldialkylammonium chloride.

CFR sections that contain labeling requirements that are exempted from disclosure requirements because they are covered under a different PRA package are listed in Tab 10.

CFR sections that contain labeling requirements that are exempted from disclosure requirements because they provide exact language to be used are listed in Tab 11.

CFR sections that contain labeling requirements that are exempted from disclosure requirements because FDA provides a sufficiently precise statement are listed in Tab 12.

Food additive regulations subject to PRA with one-time data submission prior to 1980 (exempt) are listed in Tab 13.

## **(2) How by Whom and For What Purpose Information Used**

Food additive petitions, submitted by food manufacturers or food additive manufacturers, are reviewed by FDA scientific personnel to ascertain if the data establish the identity of the substance, its use in/on the food, and to establish that the intended use in food is safe. The petitions themselves may contain privileged information and will not be directly published. Favorable action on the petition requires publication of a regulation in the **Federal Register** establishing the conditions under which the additive may be safely used in food.

The labeling information for food, such as proper name of the product, the name and address of the manufacturer of the product, and other requirements such as net weight statements, are specifically required by FFDCa and other Acts enforced by FDA.

Previously, food additive petitions provided the only method for premarket safety review and approval of food additives required by law. Without such petitions, there was no legal way to bring new products to market.

In a final rule published on July 17, 1995 (60 FR 36583), a threshold of regulation (TOR) exemption from the food additive petition requirement was established. Under 21 CFR 170.39, substances used in food packaging or food processing equipment that are not designed to have a technical effect in or on the food itself and which migrate into food at levels below a specified threshold limit may be marketed through the TOR review process, instead of submitting a food additive petition. In November, 1997, Section 309 of the FDA Modernization Act (FDAMA) amended Section 409 of FFDCa to establish another exemption from the food additive petition requirement, a premarket notification process for "food contact substances." New products, meeting the definition of a "food contact substance," may now be brought to market through a Food Contact Notification (FCN) process, instead of submitting a food additive petition (Section 409(h)) (Tab 1).

We estimate that FDA's acceptance of FCN's may reduce the submission of food additive petitions by as much as 75%. However, for direct food additives, some secondary direct food additives (processing aids), and a few indirect food additives (packaging and food processing equipment), food additive petitions remain the only legal way to bring new products to market. Failure to provide requirements for petitions would prevent industry from preparing petitions sufficient to permit new products and would make Federal programs for petition review inefficient.

## **(3) Consideration of Information Technology**

The availability of computerized indexing services such as Med-Line and Tox-Line permits petitioners to search the scientific literature for safety data on new or existing food additives. FDA has also instituted, internally, a computerized indexing system (SIREN: Scientific Information Retrieval and Exchange Network). Under the Food Additives Regulatory Management (FARM) Project, FDA has implemented a new image-based information management system. This system contains capture, full-text indexing and retrieval, document management, workflow and tracking

modules. FARM will permit FDA personnel to easily locate and access all new and previously submitted petition, notification, and related data.

Under the FARM Project, the agency established a working group LAN. Both back-filed and currently active petitions have been scanned and indexed into our FARM system. The FARM Electronic Document Management and Information system is in place and training of agency personnel in handling of petitions in electronic format and in performing related activities, such as responding to electronic Freedom of Information (EFOI) requests, will be completed shortly.

In a Federal Register final rule of March 20, 1997 (62 FR 13464), FDA published 21 CFR Part 11, Electronic records; electronic signatures. These regulations apply to all FDA program areas and to any paper records required by statute or agency regulations. On January 28, 1999 (64 FR 4433), FDA

announced the availability of guidance for industry on "Providing Regulatory Submission in Electronic Format - General Considerations." The Office of Premarket Approval (OPA) participated in a number of the discussions and meetings with CDER, CBER and other centers on agency standards for electronic submissions. These discussions were designed to ensure that agency-wide requirements are generally suitable for all electronic submissions to the agency, including those for food and color additive petitions under 21 CFR 71.1 and 171.1. OPA is currently drafting general and specific guidance documents for electronic submission of the various types of petitions and notifications which it receives, including food additive petitions.

The labeling requirements of Parts 172 and 173 do not prohibit the use of improved technology that may be appropriate to satisfy the requirements. The primary type of information collection being described here is the food additive container label instructions for safe use, information which the food additive manufacturer already has available.

#### **(4) Identification of Duplication and Similar Information Already Available.**

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.

The Antimicrobial Regulation Technical Corrections Act of 1998 restores FDA's regulatory authority for certain uses of antimicrobials that were earlier given to EPA by the Food Quality Protection Act of 1996. FDA provides guidance to industry (for petitions or notifications) on antimicrobial food additives through its website at "<http://vm.cfsan.fda.gov/~dms/opa-antg.html>".

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 of the use of a substance in meat and poultry products. Recently, USDA/FSIS (60 FR 67459, December 29, 1995) and FDA (60 FR 67490, December 29, 1995), proposed to amend their regulations to harmonize and improve the efficiency of the procedures used by USDA/FSIS and FDA with respect to reviewing and approving the use of substances in meat and poultry. Consequently, FDA and FSIS entered into a memorandum of understanding (MOU) (May 19, 1999 (64 FR 27274)). Under the terms of the MOU, petitions to use a food or color additive or GRAS substance in the production of meat or poultry products are evaluated for safety by FDA and for suitability by FSIS. On December 23, 1999 (64 FR 72168), FSIS amended the Federal meat and poultry products inspection regulations to eliminate the need for separate FSIS rulemakings. FDA is currently preparing a final rule amending its regulations on petitions for the use of food ingredients and sources of radiation to permit an efficient joint review by both FDA and FSIS. These documents resulted from a coordinated effort by the two agencies to ease the paperwork burden on regulated industries through streamlining the government's food ingredient approval process for substances used in meat and poultry products.

The Bureau of Alcohol, Tobacco, and Firearms (BATF) exempts certain alcoholic beverages from the FDA labeling requirements for retail sale, but does not issue exemptions for labeling of the additives at the manufacturing level. As set out in 27 CFR 24.247 and 24.248, BATF relies upon FDA regulations and opinions for safety evaluations of alcoholic beverage additives.

In a notice of November 28, 1994 (59 FR 60870), FDA announced the availability of a draft policy on its development and use of standards with respect to international harmonization of regulatory requirements and guidelines. In a notice of October 11, 1995 (60 FR 53078), the agency addressed comments received in response to the November 28, 1994 notice and published the text of its policy on international harmonization of regulatory requirements and guidelines. It is the intent of this policy to enable FDA to: (1) continue to participate in international standards activities that assist it in implementing statutory provisions for safeguarding the public health; (2) increase its efforts to harmonize its regulatory requirements with those of foreign governments, including setting new standards that better serve public health; and (3) respond to laws and policies such as the Trade Agreements Act and OMB Circular No. A-119 that encourage agencies to use international standards that provide the desired degree of protection. FDA has followed up on this policy with an advance notice of proposed rulemaking (62 FR 36243, July 7, 1997) announcing that the agency is considering the amendment of its regulations to establish procedures for the systematic review of standards and related texts adopted by the Codex Alimentarius Commission (Codex). Codex is an international body that establishes food standards under the joint auspices of the United Nations World Health Organization and Food and Agriculture Organization.

In addition, The Center for Food Safety and Applied Nutrition has developed an International Affirmative Agenda for the next three years (2000-2002). This Agenda is publically available in FDA's Dockets Management Branch (Docket No. 99N-3089) (64 FR 71145, December 20, 1999).

Existing data are utilized by FDA in evaluating a food additive petition. Data in FDA files can be

cross-referenced, data available in the scientific literature can be submitted, and data gathered for other government agencies such as USDA and EPA may be submitted in support of a food additive petition. Food additives are exempt from the provisions of the Toxic Substances Control Act, so that data on safety and environmental concerns developed by the petitioner for a food additive petition need not be duplicated. However, existing safety data from feeding studies sometimes are not considered adequate by contemporary scientific standards and may need to be supplemented with new data.

The labeling information required for specific food additives covered by this submission is already available and can be used or modified for labeling use. This information can be made available only by the firm manufacturing the food additive.

### **(5) Small Businesses**

There is no known way to minimize the burdens on a small business wishing to petition for a new food additive or food additive use. The agency has established criteria as to the type of data necessary to demonstrate the safety of a food 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 are the same regardless of the size of the firm. However, FDA helps small business to deal with the labeling requirements through the scientific and administrative staffs within the agency.

### **(6) Consequences of Less Frequent Information Collection and Technical Or Legal Obstacles**

Companies have a right, granted by law, to submit food additive petitions in order to permit marketing of a new food additive or to expand the usage of a currently regulated food additive. Restriction of this right would lower the number of food additives being cleared for use and would have no detrimental effects on Federal activities.

The consequence of discontinuing labeling requirements would be the possible misuse of food additives, resulting in the introduction of unsafe food into interstate commerce. Each container of a food additive must be properly labeled to assure safe use of the additive and to safeguard the public health. Additionally, food ingredients must be identified on the label of retail packages of foods.

Section 409(a) of the Federal Food, Drug and Cosmetic Act specifies that a food additive is unsafe unless it conforms to a regulation prescribing the conditions under which it may safely be used, or unless it is exempted by regulation for investigational use, or an effective food contact notification was submitted under Section 409(h). Section 409(b) of FFDCA specifies the information that must be submitted by a petitioner in order to establish the safety of a food additive and to secure the issuance of a regulation permitting its use.

21 CFR Part 171 provides a standard format for food additive petitions in order to facilitate the processing of the petition and hence the issuance of a regulation as required by FFDCFA.

**(7) Special circumstances**

Data collection for food additive petitions involves no special circumstances and all information would be collected in conformance with the Paperwork Reduction Act.

**(8) Outside Consultation**

In accordance with 5 CFR 1320.8(d), on May 16, 200 (65 FR 31178), a 60-day notice for public comment (Tab 14) was published in the Federal Register. No comments were received from the public.

The regulations in 21 CFR regarding the submission of food additive petitions were subject to notice and comment rulemaking at the time they were promulgated (1959). All regulations published in response to food additive petitions are also subject to notice and comment rulemaking.

The issues concerning the labeling regulations have been subject to public comment under the Administrative Procedures Act and incorporated as part of routine rulemaking activities. Any comments received in response to the labeling requirements were reviewed and the differences resolved prior to promulgation of final regulations. The comments and the responses cannot be reconstructed at this point because the files containing these documents have either been lost or destroyed in the more than 25 years that have elapsed since the promulgation of the regulations.

In 1987, the agency announced the availability of guidelines for formatting food additive, color additive, and generally recognized as safe (GRAS) affirmation petitions prepared for submission to the FDA. These guidelines were in response to requests from industry for guidance in the preparation of these petitions. A contractor, working with the Center for Food Safety and Applied Nutrition's petitions data base, developed guidelines for organizing and arranging the data and copies of the subject petitions. The guidelines are not requirements of FDA but represent a suggested format that can be followed by a petitioner if so desired. Legal requirements for submission of food additive, color additive and GRAS affirmation petitions outlined in 21 CFR Parts 71, 170, and 171 were not affected by the guidelines.

In 1994, the agency prepared an information and guidance package for the submission of food additive petitions. This package contains copies of relevant FDA regulations and recommendations for preparing toxicology, chemistry, and environmental information. These recommendations are updated as required. This package is made available to anyone requesting information on the preparation of a food additive petition in hard copy. Guidance for submitting a food additive, color additive, or GRAS petition is also available on the web at "<http://vm.cfsan.fda.gov/~dms/opa-toc.html>".

The agency meets regularly with petitioners prior to petitioning and during petition review to ensure that data collected are those necessary and sufficient to reach a decision on a petition.

Examples of persons and companies engaged in such consultation follows:

<u>Name</u>	<u>Firm</u>	<u>Telephone No.</u>
Allgood, Greg	Procter and Gamble	513-634-6808
Harrison, Eliot	Lewis and Harrison	202-393-3903
Heimbach, James	Environ	
Marrapesc, Martha	Keller and Heckman	202-434-4123
Peterson, Robert	Monsanto	847-581-5405
Yingling, Gary	McKenna and Cuneo	202-789-7645

The purpose of the consultations is to offer guidance on specific testing requirements for a new additive or a new use of a previously regulated additive. Any unresolved issues are usually the subject of a future consultation. Any policy issues would be referred to FDA management for consideration.

In general, the public sector has no involvement with data developed for food additive petitions. Public opportunity for comment on a food additive is given at the time a filing notice is published in the **Federal Register** and the public may, within 30 days of the publication of a regulation authorizing a new food additive, submit objections. Additionally, all safety data submitted are subject to release under the Freedom of Information Act.

#### **(9) Payment to Respondents**

No payment or gift is provided to respondents.

#### **(10) Confidentiality of Information**

Because food additive petitions often contain trade secret information, all files are maintained in a secured area. Confidentiality of data and information in food additive petitions is regulated under 21 CFR 171.1. The information is also safeguarded by Section 301(j) of FFDCA.

#### **(11) Sensitive Questions**

There are no questions of a sensitive nature in the food additive petition requirements.

#### **(12) Burden Hours and Explanation**

The total number of food additive petitions received in fiscal year 1999, was 51. Based on petition data, these 51 were divided into 10 petitions for direct addition of additives to food and 41 for material used to manufacture food-contact articles such as packaging and food processing equipment (indirect additives). The burden of the data collection for food additive petitions varies with the type of petition submitted. The labeling requirements for food additives were designed to specify the minimum information needed for labeling in order that food 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 additive regulation. Label information does not have any specific record-keeping requirements unique to preparing the label. The labeling requirements set forth in the food additive regulations apply primarily to labeling of the food additive at the manufacturing level. Labeling of food additive containers by the manufacturer of the additive provides the information necessary to enable a food manufacturer to use the food additive safely, in conformance with all applicable FDA regulations.

In the previous supporting statement for extension of OMB approval of this information collection, food additives petitions were divided into seven categories (four categories of indirect additive petitions and three categories of direct additive petitions), depending on the complexity of their testing requirements. We estimate that all of the indirect additive petitions previously included under the categories for simple and average petitions and approximately one-half of the indirect additive petitions previously included under the category of petitions with complex analytical problems may now be eligible for submission as Food Contact Notices. In addition, we estimate that approximately 20-30% of direct additive petitions previously included under the average petition category may now be eligible for submission as Food Contact Notices (namely, some secondary direct food additive petitions).

The following examples represent estimates of information collection burden for food additive petitions. These include only expected petitions for food additives not eligible for exemption under new Section 409(h) of FFDCA.

Category 1. For an indirect additive petition with complex analytical problems, the estimated time requirement per petition is approximately 3990 hours. An average of 4 petitions of this type is received on an annual basis, resulting in a burden of 15,960 hours.

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. However, very few such petitions have been received in recent years so we are not including this potential charge against OMB No. 0910-0016 at this time.

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 (a reduction of 40 hours from the previous estimate, due to categorical exclusion from previous requirement of providing an environmental assessment), including analytical work and administrative details. No toxicological studies are required. An average of one petition of this type is received on an annual basis, 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 seven petitions of this type is received on an annual basis, resulting in a burden of 25,200 hours.

Category 5. A petition for a previously unregulated direct food additive would require approximately 28,000 hours per petition (long-term toxicological studies, analytical work, administrative details). An average of one petition of this type is received on an annual basis, resulting in a burden of 28,000 hours.

The following summaries list the petition categories and the burden for each.

Estimated Annual Reporting Burden					
CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
21 CFR 171.1					
Category 1	4	1	4	3,990	15,960
Category 2	0	1	0	18,000	0
Category 3	1	1	1	160	160
Category 4	7	1	7	3,600	25,200
Category 5	1	1	1	28,000	28,000
Total	13	1	13	53,750	69,320 <sup>2</sup>

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup>This number is different than the 60 day notice May 16, 2000 (65 FR 31178) due to rounding of total hours.

### (13) Annual Cost to Respondents

Furnishing the information required even in a simple petition requires a team of professional employees, which may include toxicologists, chemists, environmental scientists, and lawyers. Assuming that the aggregate professional hourly cost is \$90, the annual cost to respondents is 6.2 million dollars (69,320 burden hours x \$90/hour).

The Food and Drug Administration has been accepting food additive petitions since 1959. There are no fees required for the submission of food additive petitions. There are no capital or start up costs to respondents.

### (14) Annual Cost to Federal Government

For fiscal year 1999, the Food and Drug Administration reports 25.9 person-years of professional time in the review of food additive petitions. Based on an average cost of \$110,000 per fully

supported position, the cost of processing food additive petitions in fiscal year 1999 was \$2,850,000. The annualized cost to the federal government of processing petitions is derived by multiplying the person-years used in processing petitions by the dollar value per supported position. We estimate that FDA's acceptance of FCN's may reduce the submission of food additive petitions by as much as 75%. Since mainly simple food additive petitions will be eligible for exemption from petitioning under new Section 409(h) of FFDCA, the expected reduction in annualized cost to the federal government of processing petitions is estimated to be approximately 50%.

**(15) Explanation of Change in Items 13 and 14**

The current OMB inventory for food additive petitions (OMB No. 0910-0016) is 126,560 burden hours. The estimated annual reporting burden is 69,320 burden hours. This expected decrease of 57,240 burden hours is due to an amendment to FFDCA (new Section 409(h)), which established a food contact notification exemption to the food additive petition requirement. This expected decrease is explained in detail above.

**(16) Statistical Reporting**

Food additive petitions are submitted for regulatory purposes and the data in these petitions are not intended for statistical use. Notification is published in the **Federal Register** when a food additive petition is filed (in accordance with 21 CFR 171.1) and when a regulation has been promulgated (in accordance with 21 CFR 171.100).

**(17) Expiration Date on Form**

No approval is being sought to not display the expiration date for OMB approval of the information collection.

**(18) Exception to Certification Statement**

There are no exceptions to the certification statement identified in Item 19, "Certification for Paperwork Reduction Act Submissions," of OMB Form 83-I.

**Tab 10**

CFR sections that are labeling requirements and are exempt because these requirements are covered under a different PRA package

- PART 170, Subpart C
- 170.60
  - Applies to specific FDA rulings and decisions on food additives
  - Labeling requirements for nitrites and/or nitrates used in meat curing mixes.
- PART 172
  - Applies to food additives for direct human consumption.
  - 172.110(c)(1)
    - Name of the Food Additive.
  - 172.115(c)(1)
    - Name of the Food Additive.
  - 172.120(c)(1)
    - Name of the Food Additive.
  - 172.133(c)(1)
    - Name of the Food Additive.
  - 172.135(c)(1)
    - Name of the Food Additive.
  - 172.170(b)(1)(i)
    - Name of the Food Additive.
  - 172.175(b)(1)(i)
    - Name of the Food Additive.
  - 172.177(e)(1)
    - Name of the food additive.
  - 172.215(d)(1)(i)
    - Name of the food additive.
  - 172.320(e)(1)
    - The name of the food additive.
  - 172.372(e)(1)
    - The name of the food additive.
  - 172.375(b)(1)
    - The name of the additive.
  - 172.430(c)(1)
    - Name of the food additive.
  - 172.665(f)(1)
    - Name of the food additive.
  - 172.695(f)(1)
    - Name of the food additive.
  - 172.730(b)(1)
    - Name of the food additive.
  - 172.800(d)
    - Cross reference to Part 105.
  - 172.804(e)
    - Cross reference to Part 105.
  - 172.806(b)(1)(i)
    - Name of the food additive.
  - 172.811(d)(1)
    - Name of the food additive.
  - 172.818(c)(1)
    - Name of the food additive.
  - 172.831(d)
    - Cross reference to Part 105.
  - 172.832(c)(1)
    - Name of the food additive.
  - 172.836(d)(1)(i)
    - Name of the food additive.
  - 172.838(d)(1)(i)
    - Name of the food additive.
  - 172.840(d)(1)(i)
    - Name of the food additive.
  - 172.841(d)
    - Cross reference to Part 105.
  - 172.842(d)(1)(i)
    - Name of the food additive.
  - 172.844(d)(1)(i)
    - Name of the food additive.
  - 172.860(e)(1)
    - Name of the food additive.
  - 172.862(d)(1)
    - Name of the food additive.
  - 172.863(c)(1)
    - Name of the food additive.

**Tab 10**

Part 173

173.310(e)(1)

173.315(d)(1)

173.320(c)

- Applies to additives used in the production of food or food additives, but not added directly to food for an intended effect.
- Name of the food additive.
- Name of the food additive.
- Conformance with EPA.

Part 178

178.1010(d)

- Applies to indirect food additives
- Conformance with FIFRA labeling.

PART 180

180.37(f)(1)(i)

180.371f(2)(i)

180.37(f)(2)(iii)

- Applies to food additives with interim approval pending further studies.
- Name of the food additive.
- Name of food additive (retail packaging).
- Cross reference to Part 105.

**Tab 11**

CFR sections that are labeling requirements that are exempt because they provide exact language.

- |                      |  |
|----------------------|--|
| PART 172             | - Applies to food additives for direct human consumption.    |
| 172.170(b)(3)        | - Retail packaging warning labels.                           |
| 172.175(b)(3)        | - Retail packaging warning labels.                           |
| 172.330(b)(1)        | - The name of the food additive.                             |
| 172.385(f)(1,3)      | - The name of the food additive.                             |
| 172.575              | - Name of the food additive.                                 |
| 172.615(c)           | - Name of the food additive.                                 |
| 172.620(d)           | - Name of the food additive.                                 |
| 172.626(c)           | - Name of the food additive.                                 |
| 172.655(d)           | - Name of the food additive.                                 |
| 172.660(c)           | - Name of the food additive.                                 |
| 172.665(f)(1)        | - Designation food grade.                                    |
| 172.695(f)(1)        | - Designation food grade.                                    |
| 172.725(c)(1)        | - Name of the food additive.                                 |
| 172.725(d)(1)        | - Specific label wording of concentrations and nomenclature. |
| 172.725(d)(2)        | - Specific label wording for use of the food additive.       |
| 172.730(c)           | - Specific label wording for use of the food additive.       |
| 172.802(d)(1)        | - Name of the food additive.                                 |
| 172.804(d)(2)        | - Label directions for use of the food additive.             |
| 172.814(c)(1)        | - Name of the food additive.                                 |
| 172.822(c)(1)        | - Name of the food additive.                                 |
| 172.834(d)           | - Name of the food additive.                                 |
| 172.841(e)           | - Label warning statement wording.                           |
| 172.858(c)(1)        | - Name of the food additive.                                 |
| 172.860(e)(2)        | - Designation food grade.                                    |
| 172.862(d)(2)        | - Designation food grade.                                    |
| 172.863(c)(2)        | - Designation food grade.                                    |
| 172.867(e)(1-3)      | - Label warning statement wording.                           |
| 172.892(preamble)    | - Name of the food additive.                                 |
| 172.894(c)(1)        | - Name of the food additive.                                 |
| 172.894(c)(2)        | - Name of the food additive.                                 |
| 172.894(c)(3)        | - Name of the food additive.                                 |
| 172.894(c)(4)        | - Name of the food additive.                                 |
| <br>                 |  |
| Part 173             | - Applies to secondary direct food additives.                |
| 173.345(c)(1)(i,iii) | - Name of the food additive and designation food grade.      |
| 173.355(c)(1)(i,ii)  | - Name of the food additive and designation food grade.      |
| 173.360(c)(1)(i,iii) | - Name of the food additive and designation food grade.      |

**Tab 11**

Part 175  
175.105(b)

- Applied to indirect food additives.
- Name of the food additive.

Part 178  
178.3520(c)

- Applied to indirect food additives.
- Name of the food additive.

PART 180  
180.25(e)

- Applies to food additives with interim approval pending further studies.
- Specific label warning statement.

## Tab 12

CFR sections that are labeling requirements and are exempt because FDA provides a sufficiently precise statement

- |                     |   |
|---------------------|---|
| PART 172            | - Applies to food additives for direct human consumption.   |
| 172.110(c)(2)       | - Percentage labeling requirement.  |
| 172.115(c)(2)       | - Percentage labeling requirement.  |
| 172.170(b)(1)(ii)   | - Concentration labeling requirement.   |
| 172.170(b)(2)       | - Retail package labeling instruction.  |
| 172.175(b)(1)(ii)   | - Concentration labeling requirement.   |
| 172.175(b)(2)       | - Retail package labeling instruction.  |
| 172.215(d)(1)(ii)   | - Concentration labeling requirement.   |
| 172.320(e)(2)       | - Labeling requiring amounts in mixture.  |
| 172.330(b)(2)       | - Concentration labeling requirement.   |
| 172.372(e)(2)       | - Labeling requiring amounts in mixture.  |
| 172.375(b)(2)       | - Concentration labeling requirement.   |
| 172.623(e)          | - Labeling requirement on presence of polysorbate 80.   |
| 172.725(c)(2)       | - Concentration labeling requirement.   |
| 172.725(c)(4)       | - Cross reference to § 172.725(d).  |
| 172.802(d)(2)       | - Concentration labeling requirement.   |
| 172.804(d)(1)       | - Concentration labeling requirement.   |
| 172.806(b)(1)(ii)   | - Concentration labeling requirement.   |
| 172.836(d)(1)(ii)   | - Concentration labeling requirement.   |
| 172.838(d)(1)(ii)   | - Concentration labeling requirement.   |
| 172.840(d)(1)(ii)   | - Concentration labeling requirement.   |
| 172.842(d)(1)(ii)   | - Concentration labeling requirement.   |
| 172.844(d)(1)(ii)   | - Concentration labeling requirement.   |
| <br>                |   |
| Part 173            | - Applies to additives used in the production of food or food additives, but not added directly to food for an intended effect. |
| 173.25(c)(3)        | - Cross reference to §173.(c)(2).   |
| 173.345(c)(1)(ii)   | - Percentage labeling requirement.  |
| 173.360(c)(1)(ii)   | - Percentage labeling requirement.  |
| <br>                |   |
| PART 180            | - Applies to food additives with interim approval pending further studies.  |
| 180.37(f)(1)(ii)    | - Concentration labeling requirement.   |
| 180.37(f)(2)(ii)(a) | - Amount of food additive - labeling of beverages.  |
| 180.37(f)(ii)(b)    | - Amount of food additive - packaging labeling for tabletop or cooking uses.  |
| 180.37(f)(2)(ii)(c) | - Amount of food additive - labeling of processed foods.  |

**Tab 13**

Food additive regulations subject to PRA with one time data submission prior to 1980 (exempt).

- PART 180
  - Applies to food additives with interim approval pending completion for additional testing.
- 180.22(b)
  - Requirements for submission of analytical data on acrylonitrile copolymers.
- 180.22(c)(1)
  - Requirements for submission of analytical data on repeated use articles - initial use.
- 180.22(c)(2)
  - Same - equilibrium extraction.
- 180.22(c)(3)
  - Estimation of migration from repeated use articles over their useful life.
- 180.22(d)
  - Procedures for calculating exposure from use of acrylonitrile copolymers as minor components of a polymer system.
- 180.22(e)
  - Toxicological testing requirements.
- 180.22(f)
  - Submission of food additive petitions for acrylonitrile copolymers.
- 180.25(f)
  - Toxicological testing requirements.
- 180.30(b)
  - Toxicological testing requirements.

## Listing of Tabs

- |                    |   |
|--------------------|---|
| Tab 1              | Section 409(a) and (b) of the Federal Food, Drug and Cosmetic Act   |
| Tab 2              | 21 CFR 171.1  |
| Tab 3              | 21 CFR Part 172   |
| Tab 4              | 21 CFR Part 173   |
| Tab 5-8            | 21 CFR Parts 174-178  |
| Tab 9              | 21 CFR Part 180   |
| Tab 10-12          | CFR sections that are labeling requirements and are exempt because these requirements are covered under a different PRA package |
| Tab 13<br>(exempt) | Food additive regulations subject to PRA with one-time data submission prior to 1980  |
| Tab 14             | Federal Register Notice May 16, 2000 (65 FR 31178)  |