Supporting Statement for Food Additive Petitions
(OMB No. 0910-0546)

A. Justification

1. Circumstances Which Make This Information Collection Necessary

Section 409(a) 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. Food additives include all substances not exempted under certain provisions of the FFDCA (section 201(s), the intended use of which results or may reasonably be expected to result, directly or indirectly, either in their becoming a component of food or otherwise affecting the characteristic of food. Section 409(b) of FFDCA specifies the information that must be submitted by a petition 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 571 of 21 CFR. These procedural regulations are designed to specify more thoroughly the information that must be submitted by the petitioner to meet the requirement 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 and provide a standard format for submission to help speed the Agency's review of the petition. Labeling requirements for food additives intended for animal consumption are also set forth in various regulations contained in Part 573. The labeling regulations are considered by FDA to be cross referenced to 571.1, which is the subject of this same OMB clearance for food additive petitions.

There is no form or application for submitting a Food Additive Petition. The kinds of data that must be submitted by the petitioner and the format which the food additive petition must follow when sent to FDA are described, (example petition letter uploaded in ROCIS). While the actual content may vary from petition to petition depending primarily on the food additive`s composition and intended use, each of the following areas must be addressed: (1) The petition shall state the petitioner's name, post office address and the name of the food additive and proposed use. (2) human food safety, (3). target animal safety, (4) environmental impact, (5) utility, (6) labeling, (7) the proposed regulation, (8) assay methodology and (9) manufacturing process and controls

Food additive petitions submitted to the Center for Veterinary Medicine (CVM) , falls into one of two categories , " moderate" or "complex," as discussed in item in detail under item 12 of this supporting statement. After a petition has been filed, the petitioner may submit additional information or data in support thereof.

2. How, by Whom and the Purpose for Collecting This Information

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, justify its intended effect in/on the food, and establish that its intended use in/on food is safe. The petitions themselves may contain privileged information that will not be made public and will not be directly published. However, favorable action on the petition by the Agency 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 animal 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. Labeling information for foods consumed by animals often includes specific directions for use.

Food additive petitions provide the only method to bring new food additives to market.

3. Use of Technology to Reduce the Burden on the Public

FDA expects that food additive petitions under 21 CFR 571.1. and Part 573 do not prohibit the use of improved technology that may be appropriate to satisfy the labeling requirements for food additives.

4. Identification and Use of Duplicate Information

There are no other regulations or Federal Agencies that require the submission of the same type of information. There is no similar data/information that could be substituted for that required by these regulations.

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.

5. FDA's Efforts to Reduce Burden on Small Business

There is no impact on small business or other small entities.

6. Impact of Not Collecting This Information or Collecting Information Less Frequently

Companies have a right, granted by law, to submit food additive petitions in order to obtain approval to market a new food additive or to expand the use of a currently regulated approved food additive. Restriction of this right would lower the number of food additives being cleared for use but 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 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. 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 571 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 FFDCA.

7. Special Circumstances That Occur When Collecting This Information

There are no special circumstances for the collection of the information requirements.

8. Efforts to Obtain Comments on the Information Collection before Submission to OMB.

In accordance with 5 CFR 1320.8(d), on October 6, 2009(74 FR51287), a 60-day notice for public comment 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 agency meets regularly with petitioners prior to the official submission of a petition and during petition review to ensure that data collected are those necessary and sufficient to reach a decision on a petition.

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 data and information submitted, except for trade secret information, are subject to release under the Freedom of Information Act after the food additive has been approved.

9. Payment or Gifts Offered to Respondents

No payment or gift is provided to respondents.

10. Method of Ensuring Respondent Confidentiality

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 571.1. The information is also safeguarded by Section 301 (j) of FFDCA.

11. Use of Sensitive Questions

This information does not contain questions pertaining to sex behavior, attitude, religious beliefs, or any other matter commonly considered private or of a sensitive nature. There are no questions of a sensitive nature in the food additive petition requirements.

12a. Burden Hours and Cost Associated With This Information Collection

Estimated Annual Reporting Burden[1]					
21 CFR Section	No. of Respondents	Annual Frequency of Response	Total Annual Responses	Hours per Response	Total Hours
571.1(c) moderate category	1	1	1	3,000	3,000
571.1(c) complex category	1	1	1	10,000	10,000
571.6 amendment of petition	2	2	4	1300	5200
Total Hours	4	4	6	14,300	18,200

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Food additive petitions submitted to CVM are estimated to fall into one of two categories of complexity that also can be used to represent estimates of the 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. Fluctuations in the number and types of food and color additive petitions received in any given year are governed by market forces.

571.1(c) moderate category: For food additive petition without complex chemistry, manufacturing, efficacy or safety issues, the estimated time requirement per petition is approximately 3,000 hours. An average of 1 (one) petitions of this type is received on an annual basis, resulting in a burden of 3,000 hours.

571.1(c) complex category: For a food additive petition with complex chemistry, manufacturing, efficacy and/or safety issues, the estimated time requirement per petition is approximately 10,000 hours. An average of 1 (one) petition of this type is received on an annual basis, resulting in a burden of 10,000 hours.

571.6: For a food additive petition amendment, the estimated time requirement per petition is approximately 1,300 hours. An average of 4 (four) petitions of this type is received on an annual basis, resulting in a burden of 5,200 hours.

The estimated annual burden for this information collection is 18,200 hours.

12b Annualized Cost Burden

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Animal Food Manufacturers	18,200	$35.00	$637,000

13. Estimates of Other Total Annual Costs to Respondents

There is no capital or start up cost to respondents.

14. Annual Cost Estimate to FDA

We anticipate that the review of a food additive petition will require the services of a GS-14 review scientist for 1000 hours at an hourly rage of $51.40 per hour. The cost for the one-time review would be $51,400.

15. Explanation for Program Changes or Adjustments

There was no change in the current burden estimate.

16. Publishing the Results of This Information Collection.

There are no results to publish for this information collection. 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 57 1.1) and when a regulation has been promulgated (in accordance with 21 CFR 571.100).

17. Reason for Not Displaying the OMB Approval Date

FDA is not seeking approval to exempt display of the expiration date for OMB approval.

18. Explanations to Section 19, Certification for Paperwork Reduction Act Submissions

There are no exceptions to Item 19 of OMB Form 83-I.