Food Additive Petitions and Investigational
Food Additive Exemptions – 21 CFR 571 and 570.17

OMB Control No. 0910-0546
SUPPORTING STATEMENT

A. Justification

1. Circumstances Which Make This Collection of Information Necessary

Section 409(a) of the Federal Food, Drug and Cosmetic Act (FFDCA) (21 U.S.C. 409(a)) 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. 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 for food additives intended for animal consumption. This information collection supports these regulations, specifically:

21 CFR 571.1; Petition
21 CFR 571.6; Amendment of Petitions

2. Purpose and Use of the Information Collection

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 animal 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 contents 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 for approval of food additives to bring new food additives for animal consumption to market.

3. Use of Improved Information Technology and Reduction Burden

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. FDA regulations (21 CFR Part 571) provide a standard format for food additive petitions in order to facilitate the processing of the petition and hence the issuance of a regulation for animal food use as required by FFDCA.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of any duplicative information collection. FDA continues to work with EPA and USDA to eliminate areas of duplicate data collection and evaluation. Memoranda of understanding have been reached with EPA in the areas of pesticides and water treatment. Also, 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. Impact on Small Businesses and Other Small Entities

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

6. Consequences of Collecting The 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 for use in animal food. 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 animal 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 animal foods.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

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

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice soliciting public comment regarding the collection of information in the Federal Register of October 21, 2015 (80 FR 63795). No comments were received.

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 comments from the public. Also, 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. However, opportunity for public 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 petition has been filed.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift is provided to respondents.

10. Assurance of Confidentiality Provide to Respondents

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. Justification for 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.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden

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

We base our estimate of the total annual responses on submissions received during fiscal years 2014 and 2015. We base our estimate of the hours per response upon our experience with the petition and filing processes.

Table 1 – Estimated Annual Reporting Burden; Food Additive Petitions[1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Avg. Burden per Response	Total Hours
571.1(c) moderate category	12	1	12	3,000	36,000
571.1(c) complex category	12	1	12	10,000	120,000
571.6 amendment of petition	2	1	2	1,300	2,600
Total					158,600

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

571.1(c) moderate category: For a food additive petition without complex chemistry, manufacturing, efficacy or safety issues, the estimated time requirement per petition is approximately 3,000 hours. We estimate that, annually, 12 respondents will each submit 1 such petition, for a total of 36,000 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. We estimate that, annually, 12 respondents will each submit 1 such petition, for a total of 120,000 hours.

571.6 amendment of petition: For a food additive petition amendment, the estimated time requirement per petition is approximately 1,300 hours. We estimate that, annually, 2 respondents will each submit 1 such amendment, for a total of 2,600 hours.

Table 2 – Estimated Annual Reporting Burden; Investigational Food Additive Files[1]

Authority	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Avg. Burden per Response	Total Hours
570.17; Moderate Category	4	1	4	1,500	6,000
570.17; Complex Category	5	1	5	5,000	25,000
Total					31,000

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

570.17 moderate category: For an investigational food additive file without complex chemistry, manufacturing, efficacy or safety issues, the estimated time requirement per file is approximately 1,500 hours. We estimate that, annually, 4 respondents will each submit 1 such file, for a total of 6,000 hours.

570.17 complex category: For an investigational food additive file with complex chemistry, manufacturing, efficacy and/or safety issues, the estimated time requirement per file is approximately 5,000 hours. We estimate that, annually, 5 respondents will each submit 1 such file, for a total of 25,000 hours.

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Compliance Officer	51,700	$47.00	$2,429,900

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

There are no capital or start-up costs to respondents.

14. Annual Cost Estimate to the Federal Government

The annualized cost to the federal government of processing petitions is derived by multiplying the hourly rate for the GS grade of the employee by the total hourly burden. We anticipate that the review of a food additive petition will require the services of a GS-13-3 review scientist for 1000 hours at an hourly rate of $47.10 per hour. The cost for the one-time review would be $47,100.

15. Explanation of Program Changes or Adjustments

This information collection reflects adjustments. The agency attributes these adjustments to industry trends.

16. Plans for Tabulation and Publication and Project Time Schedule

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.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

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

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.