U.S Food and Drug Administration
Food Additive Petitions and Investigational Food Additive Exemptions

OMB Control No. 0910-0546

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us or we) regulations. Section 409(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 348(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 the FD&C Act (21 U.S.C. 348(b)) specifies the information that must be submitted by a petitioner to establish the safety of a food additive and to secure the issuance of a regulation permitting its use in animal food.

To implement the provisions of § 409 of the FD&C Act, we issued procedural regulations under 21 CFR part 571. These procedural regulations are designed to specify more thoroughly the information that must be submitted to meet the requirement set down in broader terms by the FD&C Act. The regulations add no substantive requirements to those indicated in the FD&C Act, but attempt to explain these requirements and provide a standard format for submission to speed processing of the petition. Labeling requirements for food additives intended for animal consumption are also set forth in various regulations contained in 21 CFR parts 501, 573, and 579. 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.

With regard to the investigational use of food additives, § 409(j) of the FD&C Act (§ 409(j)) (21 U.S.C. 348(j)) provides that any food additive, or any food bearing or containing such an additive, may be exempted from the requirements of this section if intended solely for investigational use by qualified experts. Investigational use of a food additive is typically to address the safety and/or intended physical or technical effect of the additive.

To implement the provisions of § 409(j), we issued regulations under 21 CFR 570.17. These regulations are designed to specify more thoroughly the information that must be submitted to meet the requirement set down in broad terms by the FD&C Act. Labeling requirements for investigational food additives are also set forth in various regulations contained in 21 CFR 501. The labeling regulations are considered by FDA to be cross-

referenced to § 570.17, which is the subject of this same OMB clearance for investigational food additive files.

Accordingly, we request extension of OMB approval of the reporting requirements in the following citations:

21 CFR 571.1 – Reporting
Sets forth the information that must be submitted in a food additive petition.

21 CFR 571.6 – Reporting
Sets forth the process to amend a food additive petition.

21 CFR 570.17 – Reporting
Sets forth the exemption for investigational use and procedure for obtaining authorization to market edible products from experimental animals.

2. Purpose and Use of the Information Collection

The information collected is necessary to protect the public health. We use the information submitted by food manufacturers or food additive manufacturers to ascertain whether 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.

Respondents include individuals and the private sector (for-profit businesses).

3. Use of Improved Information Technology and Burden Reduction

The regulation does not specifically prescribe the use of automated, electronic or other forms of information technology as necessary for use by firms. Food additive petitions and requests for investigational food additive exemptions may be submitted electronically via the FDA Electronic Submission Gateway (FDA ESG). FDA estimates that 10% of the respondents will use electronic means to submit food additive petitions and requests for investigational food additive exemptions.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of any duplicative information collection. There are no other regulations or Federal agencies that require food additive petitions and requests for investigational food additive exemptions for animal food. 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 or Other Small Entities

This collection carries the same burden for small or large firms. The FD&C Act and our regulations require all respondents to submit the same information. There is no exemption from the requirements of the regulation for small businesses. We estimate that approximately one quarter of respondents, or 3 firms, are small businesses. FDA aids small businesses in complying with its requirements through the Agency's Regional Small Business Representatives and through the scientific and administrative staffs within the Agency. FDA also provides a Small Business Guide on the Agency's website at http://www.fda.gov/oc/industry/.

6. Consequences of Collecting the Information Less Frequently

Data collection occurs occasionally. All reporting requirements are one-time events associated with the respondent's petition to establish the safety of a food additive and to secure the issuance of a regulation permitting its use in animal food or respondent's request for exemption for investigational use.

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 for public comment in the *Federal Register* of August 3, 2018 (83 FR 38149). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift is provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

This information collection request (ICR) involves food additive petitions and requests for investigational food additive exemptions. It specifies the information that must be submitted by a petitioner to establish the safety of a food additive and to secure the issuance of a regulation permitting its use in animal food.

In preparing this Supporting Statement, FDA staff consulted with the FDA Privacy Office to ensure appropriate handling of information collected. FDA determined the Privacy Act of 1974 does not apply.

Confidentiality of data and information in food additive petitions is regulated under 21 CFR 571.1. In accordance with § 571.1(h)(1), certain data and information in a food additive petition generally will be made available for public disclosure after the notice of

filing of the petition is published in the Federal Register. However, food additive petitions may contain trade secret and confidential commercial information. This information is protected from public disclosure under 21 CFR 571.1(h)(2). Confidentiality of information also will be safeguarded within the provisions of our public information regulations in 21 CFR part 20. Only information that is releasable under our regulations in part 20 would be released to the public. Finally, trade secret and confidential commercial information is also safeguarded by section 301(j) of the FD&C 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)).

11. Justification for Sensitive Questions

This information collection does not involve questions that are of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

Description of Respondents: Respondents to this collection of information are food manufacturers or food additive manufacturers.

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

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

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Food Additive Petitions:					
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
Investigational Food Additive Files:					
570.17 Moderate Category	4	1	4	1,500	6,000
570.17 Complex Category	5	1	5	5,000	25,000
Total					189,600

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

We base our estimates of the total annual responses on submissions received during fiscal years 2016 and 2017. We base our estimate of the hours per response upon our experience with the petition and filing process.

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

§ 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, four respondents will each submit one 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, five respondents will each submit one 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	189,600	$50.54[1]	$9,582,384

[1] May 2017 National Industry-Specific Occupational Employment and Wage Estimates, US Department of Labor, Bureau of Labor Statistics, Compliance Officers 13-1041 (https://www.bls.gov/oes/current/oes131041.htm) $38.88 hourly wage plus 30% adjusted for benefits.

FDA estimates the cost of the information collection request to industry to be 9,582,384. This figure was calculated by multiplying the hourly wage rate for an industry compliance officer ($50.54) by the total number of burden hours (189,600).

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

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost 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 $49.56 per hour based on the 2018 pay scale in the locality pay area of Washington-Baltimore Metro. The cost for the one-time review would be $49,560.

15. Explanation for Program Changes or Adjustments

The burden for this information collection has not changed since the last OMB approval.

16. Plans for Tabulation and Publication and Project Time Schedule

We have no plans to tabulate and publish information from this information collection.

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

There are no reasons why display of the expiration date for OMB approval of the information collection would be inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.