United States Food and Drug Administration

Reporting Associated with Food Additive Petitions, Investigational Food Additive Files Exemptions, and Declaration of Color Additives on Animal Food Labels--21 CFR 501.22(k), 570.17, 571.1, and 571.6

OMB Control No. 0910-0546

Terms of Clearance: None.

SUPPORTING STATEMENT - **Part A: Justification**:

1. Circumstances Making the Collection of Information Necessary

This information collection supports FDA regulations as discussed below.

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 FD&C Act 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 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 food additive petition. Labeling requirements for food additives intended for animal consumption are also set forth in various regulations contained in parts 501, 573, and 579 (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.

Regarding the investigational use of food additives, section 409(j) of the FD&C Act 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 section 409(j) of the FD&C Act, we issued regulations under § 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 additive files are also set forth in various regulations contained in part 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

The information collection provisions approved under OMB control numbers 0910-0546, and 0910-0721 are similar in that they support FDA's regulations §§ 501.22(k), 570.17, 571.1, and 571.6. Thus, with this notice, FDA proposes to consolidate these collections of information into one OMB control number for government efficiency and to allow the public to look to one OMB control number for all reporting associated with FDA's regulations §§ 501.22(k), 570.17, 571.1, and 571.6. Upon approval of the consolidated collection OMB control number 0910-0546, we will ask OMB to discontinue OMB control number 0910-0721.

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.

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 and provides animal owners with information on the color additives used in animal food. Animal owners use the information to become knowledgeable about the foods they purchase for their animals. Color additive information enables a consumer to comparison shop and to avoid substances to which their animals may be sensitive.

3. Use of Improved Information Technology and Burden Reduction

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.

In the majority of cases (>90%), animal feed companies revise their product labels without sending their draft labels to FDA for review. Because the vast majority of animal food products that contain certified color additives are pet foods, we limit our burden estimate to reviewing labels for the use of certified color additives to pet food manufacturers subject to this regulation. For the small number of companies that will be sending their draft labels to FDA for review, about 90% will be by e-mail and 10% by mail.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

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.

With regards to food additive petitions and investigational food additive files exemptions, we estimate that approximately one quarter of respondents, or 3 firms, are small businesses.

We believe that our requirements for the declaration of certifiable color additives in animal food labeling impose the minimal burden necessary while still allowing us to comply with the FD&C Act. We estimate that approximately 3,050 respondents 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.

Reporting requirements 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 is a one-time event.

Only when a product label changes is information collected and updated. If this information is not collected, FDA would not be able to ensure the safety of the regulated products entering the marketplace.

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

There are no special circumstances for this collection of information.

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

FDA published a 60-day notice for public comment in the *Federal Register* of October 8, 2021, 86 FR 56277. Although three comments were received, they were not responsive to the four collection of information topics solicited and therefore will not be discussed in this document.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this Supporting Statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

Food Additive Petitions and Investigational Food Additive Exemptions:

This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII submitted is name of petitioner/filer and post office address. FDA determined that although PII is collected it is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, the contractor or FDA do not use name or any other personal

identifier to routinely retrieve records from the information collected. Through appropriate design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

Animal Food Labeling; Declaration of Certified and Non-Certified Color Additives:

This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII submitted is name and employer address. This information collection is to provide labeling so animal owners can have information on the color additives used in animal food. Through appropriate guidance, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

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	6	1	6	3,000	18,000
571.1(c) Complex Category	5	1	5	10,000	50,000
571.6 Amendment of Petition	5	1	5	1,300	6,500
Investigational Food Additive Files					
570.17 Moderate Category	6	1	6	1,500	9,000
570.17 Complex Category	7	1	7	5,000	35,000
Color Additives					
501.22(k); labeling of color additive or lake of color additive; labeling of color additives not subject to certification	3,120	0.8292	2,587	0.25 (15 minutes)	647
Total Hours					119,147

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Compliance Officer	118,500	$54.21[1]	$6,423,885
Industrial Production Manager	647	$73.87[2]	$47,793.89
Total			$6,471,678.89

[1] May 2020 National Industry-Specific Occupational Employment and Wage Estimates, Bureau of Labor Statistics and including 30% for benefits (https://www.bls.gov/oes/current/oes131041.htm)

[2] May 2020 National Industry-Specific Occupational Employment and Wage Estimates, Bureau of Labor Statistics and including 30% for benefits (https://www.bls.gov/oes/current/oes113051.htm).

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

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

14. Annualized Cost to the Federal Government

FDA estimates the cost to the Federal Government for this collection to be $54,253.40.

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 $53.00 per hour based on the 2021 pay scale in the locality pay area of Washington-Baltimore-Arlington. The cost for the one-time review would be $53,000 (1000 hours x $53.00).

We anticipate that the review of product labeling will require the services of a GS-12 employee for 30 hours at an hourly rate of $41.78 per hour based on the 2021 pay scale in the locality pay area of Washington-Baltimore-Arlington. The cost for reviewing product labeling would be $1,253.40 (30 hours x $41.78)

15. Explanation for Program Changes or Adjustments*

The information collection reflects a net decrease of 70,453 hours. We also experienced a net increase of 2,587 responses from 35 OMB approved annual responses to 2,616 estimated annual responses. These changes were due to the consolidating of the information collection covered by OMB control number 0910-0721 and due to estimated changes of the number of respondents for food additive petitions and investigational food additive files.

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

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

FDA will display the OMB expiration date as required by 5 CFR 1320.5

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.