UNITED STATES FOOD & DRUG ADMINISTRATION

Additives for Animal Food

OMB Control No. 0910-0546 -- REVISION

SUPPORTING STATEMENT

Terms of Clearance: None.

**Part A: Justification**:

1. Circumstances Making the Collection of Information Necessary

This information collection helps support implementation of FDA’s authority over food additives intended for use in animal food, with applicable regulations found at 21 CFR 570 and 571. Misbranded foods are prohibited under section 403 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. § 343); food additives are covered in section 409 (21 U.S.C. § 348), which provides, at section 409(a) (21 U.S.C. § 348(a)), that a food additive shall be deemed to be unsafe unless its use is permitted by a regulation that prescribes the condition(s) under which it may safely be used, or unless it is exempted by regulation for investigational use. Section 409(b) (21 U.S.C. § 348(b)) of the FD&C Act provides for petitions to establish safety of food additives and specifies information that must be submitted to FDA before a regulation permitting its use may be issued.

Agency regulation in 21 CFR part 570 sets forth general provisions applicable to food additives intended for use in animal food; provides relevant definitions; establishes principles for determining safety; and explains prescribed elements to be included in a *Generally Recognized as Safe* (GRAS) notice. The regulation also provides for certain exemptions for investigational use and discusses applicable procedures. Agency regulation in 21 CFR part 571 establishes procedural requirements for the submission of petitions filed under section 409(b) of the FD&C Act, including content and format elements to facilitate FDA processing of a food additive petition. Finally, 21 CFR part 501 establishes disclosure requirements for animal food labeling, including the disclosure of the presence of certified and noncertified color additives (501.22(k)). Additional disclosure requirements are found in 21 CFR parts 573 (food additives permitted in feed and drinking water of animals) and 579 (irradiation in the production, processing, and handling of animal food), and are included in the scope of coverage for the information collection.

Because regulations providing for approved uses of drugs and combinations of drugs in animal feeds are established in 21 CFR 558, we are revising the information collection to reference to the Animal Drug User Fee Act (ADUFA) and its recent reauthorization which incorporates FDA’s performance goals commitment letter entitled, “*Reauthorization Performance Goals and Procedures Fiscal Years 2024 Through 2028*,” available for download at <https://www.fda.gov/media/116001/download?attachment>; and the Animal Generic Drug User Fee Act (AGDUFA) and its recent reauthorization which incorporates FDA’s performance goals commitment letter entitled, “*Animal Generic Drug User Fee Act Reauthorization Performance Goals and Procedures – Fiscal Years 2024 Through 2028*,” available for download at <https://www.fda.gov/media/116001/download?attachment>. We believe the respective authorities may be pertinent for respondents to the information collection. Information collection activities attributable to the submission of new animal drug and abbreviated new animal drug applications are approved in OMB control nos. **0910-0032** and **0910-0669**, respectively.

The information collection also utilizes guidance documents, issued consistent with our Good Guidance Practice regulation at 21 CFR 10.115, which provides for public comment at any time. Guidance documents are also issued and developed consistent with current AGDUFA commitment goals. Intending to help ensure the safety of animal food, we have issued the following guidance documents:

* To assist petitioners with the preparation and submission of food additive petitions, we have issued the guidance document, “*Guidance for Industry (GFI) #221*: *Recommendations for Preparation and Submission of Animal Food Additive Petitions*” (2015), available for download from our website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-221-recommendations-preparation-and-submission-animal-food-additive-petitions>. We are currently finalizing the document to update instruction on consulting with FDA regarding animal food food-additives.
* Guidance for Industry (GFI) #262, “*Pre-Submission Consultation Process for Animal Food Additive Petitions or Generally Recognized as Safe (GRAS) Notices*” (December 2020), available for download from our website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-262-pre-submission-consultation-process-animal-food-additive-petitions-or-generally>. The guidance document describes the types of information our Center for Veterinary Medicine (CVM) recommends be included in:

1. pre-petition consultations prior to submission of food additive petitions (FAP) for food additives intended for use in animal food;
2. pre-submission consultations regarding an animal food substance for which an entity plans to provide notice of its conclusion that the intended use of the substance is generally recognized as safe (GRAS) under FDA’s animal food GRAS Notification program; or
3. a Food Use Authorization (FUA) request to permit the use, in human or animal foods, of animal products derived from animals that have been administered an investigational substance intended for use in animal food.
* GFI #294, “*Animal Food Ingredient Consultation* (AFIC)” (October 2024), available for download at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-294-animal-food-ingredient-consultation-afic>, describes the AFIC process, which provides for a way, within the regulatory framework, for firms that are developing animal food ingredients to consult with FDA, and for FDA to review information from developers and the public regarding the ingredients and any relevant safety concerns. The AFIC process includes opportunities for public awareness of, and input on, the ingredients for which FDA is providing consultation. The guidance document also explains that FDA generally would not intend to take enforcement action against an ingredient for being an unapproved animal food additive if FDA has sent an AFIC “consultation complete” letter, provided the ingredient is used in accordance with the terms described in the letter and there continues to be no questions or concerns about the safety of the ingredient.

We are therefore requesting OMB approval for the information collection provisions established in the referenced FDA regulations, as well as information collection recommendations included in the associated guidance documents, as discussed in this supporting statement.

1. Purpose and Use of the Information Collection

Respondents to the collection of information are animal food manufacturers or animal food additive manufactures. With regard to submission activities, we assume 2,508 respondents based on the number of registrants who identify as animal food additive manufacturers. With regard to labeling activities under 21 CFR 501.22(k), we assume 3,120 respondents based on information found in previous rulemaking (RIN-0910AG02) regarding declarations for animal food product labels. We use information submitted to us by respondents to help fulfill our mandate to protect the public health. Information included in petitions filed in accordance with 21 CFR part 571 enables us to ascertain the identity of the substance, whether the data justifies the substance’s intended effect in/on the food, and establishes that the substance’s intended use in/on food is safe. Petitions filed in accordance with 21 CFR part 571 may contain privileged information that will not be made publicly available by FDA. However, FDA is required to publish its regulations in the *Federal Register*, including regulations to establish the conditions under which an additive may be safely used in animal food that result from such petitions.

Similarly, information submitted to us in conjunction with pre-petition consultations is used to help facilitate FDA action on requests received. Information included in a pre-petition consultation request will not be made publicly available.

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 the FD&C Act 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.

1. 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). Information collection associated with the submission of electronic records is currently approved under OMB control number 0910-0303. FDA estimates that 10% of the respondents will use electronic means to submit food additive petitions and requests for investigational food additive exemptions.

Firms that would like to market ingredients and consult with FDA may contact FDA via email at Animalfood-premarket@fda.hhs.gov.

1. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. FDA maintains similar information collections in its inventory intended to account for activities relating to our human foods programs, however this collection of information is intended to account for activities attendant to food intended for animals exclusively.

1. Impact on Small Businesses or Other Small Entities

With regard to the annual submission of food additive petitions and investigational food additive files for animal food, we estimate that approximately 3 firms are small businesses. We believe that declaration of certifiable color additives in animal food labeling requirements impose the minimal burden necessary while still allowing compliance with the FD&C Act and estimate 1,050 annual respondents are small businesses. While we do not believe the information collection imposes undue burden on small entities, FDA also aids small businesses in complying with its requirements through its Regional Small Business Representatives and through the scientific and administrative staffs. FDA also provides a Small Business Guide on its website at <http://www.fda.gov/oc/industry/>.

1. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory and regulatory authorities.

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

There are no special circumstances for this collection of information.

1. 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 December 19, 2024 (89 FR 103838). We received one comment that, while it generally supports this collection of information, did not respond to the questions posed in § 1320.8(d).

1. Explanation of Any Payment or Gift to Respondents

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

1. Assurance of Confidentiality Provided to Respondents

*The Privacy Act of 1974*

In preparing this Supporting Statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. Although this ICR collects personally identifiable information (PII), it is collected in the context of the subject individuals’ professional capacity and the FDA-related work performed for their employer (e.g., point of contact at a regulated entity). The PII submitted is name of petitioner/filer/employer and 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 Privacy 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.

*The Freedom of Information Act (FOIA)*

Under 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.

1. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

1. Estimates of Annualized Burden Hours and Cost

*12a. Annualized Hour Burden Estimate*

Table 1.--Estimated Annual Reporting Burden1

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Regulatory Authority; Submission of Information  | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Average Burden per Response | Total Hours |
| Food Additive Petitions |
| 21 CFR 571.1(c) Moderate Category  |  3 | 1 | 3 | 3,000 | 9,000 |
| 21 CFR 571.1(c) Complex Category | 3 | 1 | 3 | 10,000 | 30,000 |
| 21 CFR 571.6 Amendment of Petition | 5 | 1 | 5 | 1,300 | 6,500 |
| Investigational Food Additive Files |
| 21 CFR 570.17 Moderate Category | 8 | 1 | 8 | 1,500 | 12,000 |
| 21 CFR 570.17 Complex Category | 10 | 1 | 10 | 5,000 | 50,000 |
| Animal Food Ingredient Consultation |
| Consultation Category | 12 | 1 | 12 | 3,000 | 36,000 |
| Amendment of Consultation | 12 | 1 | 12 | 1,300 | 15,600 |
| Color Additives |
| 21 CFR 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  | 159,747 |

We base our estimate of the total annual responses on submissions received over the last three years.

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 21 CFR 501.22(k). 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.

We have determined that food additive petitions and investigational food additive files that are submitted fall into one of two categories of complexity.

**Food Additive Petitions** -

The number of respondents is based on the average number of submissions received over the past 3 years. We base our estimate of the hours per response on our experience with the labeling, food additive petition, and filing processes.

*571.1(c) Moderate Category*: For a food additive petition without complex chemistry, manufacturing, efficacy and/or safety issues, the estimated time requirement per petition is approximately 3,000 hours. We estimate that, annually, 3 respondents will submit 1 such petition, for a total of 9,000 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, 3 respondents will each submit 1 such petition, for a total of 30,000 hours.

*571.6*: For a food additive petition amendment, the estimated time requirement per petition is approximately 1,300 hours. We estimate that, annually, 5 respondents will each submit 1 such amendment, for a total of 6,500 hours.

**Investigational Food Additive Files** -

*570.17 Moderate Category*: For an investigational food additive file without complex chemistry, manufacturing, efficacy and/or safety issues, the estimated time requirement per file is approximately 1,500 hours. We estimate that, annually, 8 respondents will each submit 1 such file, for a total of 12,000 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, 10 respondents will each submit 1 such file, for a total of 50,000 hours.

The labeling requirements for food and color additives were designed to specify the minimum information needed for labeling in order that food and color manufacturers may comply with all applicable provisions of the FD&C Act and other specific labeling acts administered by FDA. Labeling 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 or color additive regulation. Labeling information does not have any specific recordkeeping requirements unique to preparing the labeling. Therefore, because labeling requirements for a particular color additive or food additive involve information required as part of the safety review process, the burden hours for labeling are included in the estimate for §§ 501.22(k) and 571.1.

*Consultations:* The estimated time requirement per consultation is approximately 3,000 hours. We estimate that, annually, 12 respondents will request a consultation to discuss their animal food ingredient, for a total of 36,000 hours.

*Amendments to Consultations:* The estimated time requirement per consultation is approximately 1,300 hours. We estimate that, annually, 12 respondents will request an amendment consultation, for a total of 15,600 hours.

*12b. Annualized Cost Burden Estimate*

We estimate the annualized burden of hour cost to respondents for this collection of information to be $9,431,448. The cost to respondents is estimated by assuming the hourly wage of an Industry Compliance Officer who submits food additive petitions, investigational food additive files, and requests for consultations to be $58.96 per hour. We further assume the hourly wage of an Industrial Production Manager who creates labels for color additives to be $78.69.

|  |  |  |  |
| --- | --- | --- | --- |
| Type of Respondent | Total Burden Hours | Hourly Wage Rate | Total Respondent Costs |
| Industry Compliance Officer | 159,100 | $58.961 | $9,380,536 |
| Industrial Production Manager | 647 | $78.692 | $50,912 |
| Total | $9,431,448 |

1 May 2023 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 2023 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>).

1. 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.

1. Annualized Cost to the Federal Government

FDA estimates the cost to the Federal Government for this collection to be $7,130,197.

We anticipate that a consultation and 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 $60.29 per hour based on the 2024 pay scale in the locality pay area of Washington-Baltimore-Arlington, DC-MD-VA-WV-PA. The cost for the one-time review would be $60,290 (1000 hours x $60.29).

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 $50.70 per hour based on the 2024 pay scale in the locality pay area of Washington-Baltimore-Arlington, DC-MD-VA-WV-PA. The cost for reviewing product labeling would be $1,521 (30 hours x $50.70)

1. Explanation for Program Changes or Adjustments

The information collection includes program changes and adjustment. We have revised the scope of activity to include recommendations found in agency guidance pertaining to consultations. After including consultation activities in our assessment of burden, we have increased our estimate by 40,600 total hours and 24 responses, annually.

1. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

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

FDA will display the OMB expiration date and inform respondents of its significance in accordance with 5 CFR1320.5(b).

1. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.