United States Food and Drug Administration

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

OMB Control No. 0910-0721

SUPPORTING STATEMENT

Terms of Clearance: None

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

FDA has the authority under the Federal Food, Drug, and Cosmetic Act (FD&C Act) to issue regulations concerning animal food. Specifically, section 403(i) of the FD&C Act (21 U.S.C. 343(i)) requires that certified color additives used in or on a food must be declared by their common or usual names and not be designated by the collective term "colorings." Our regulations in part 501 (21 CFR part 501) set forth the requirements for animal food labeling. Under § 501.22(k) (21 CFR 501.22(k)), animal food manufacturers must declare on the animal food label the presence of certified and noncertified color additives in their animal food products. Our animal food labeling regulation at § 501.22(k) is consistent with the regulations requiring the declaration of color additives on human food labels

We therefore request extension of OMB approval of the information collection provisions found in 21 CFR 501.22(k) as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The purpose of the labeling is to provide 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

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

There is no exemption from section 403(i) of the FD&C Act for 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 assist small businesses to meet the requirements of the FD&C Act through our Regional Small Business Representatives and through the scientific and administrative staff within the Center. We estimate that approximately 3,050 respondents are small businesses.

6. Consequences of Collecting the Information Less Frequently

Data collection occurs occasionally. This information is collected and updated only when a product label is changed. 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 March 4, 2021 (86 FR 12690). We received 22 comments expressing the importance of color additive information on pet food labeling, along with other ingredient disclosures. FDA appreciates these comments; at this time, we are not revising the regulations found at § 501.22(k) related to color additive information on the labeling of animal food.

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.

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 Third-Party Disclosure Burden[1]

21 CFR Section; Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
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

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Industrial Production Manager	647	$73.87[1]	$47,793.89

[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/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 $1,253.40. This estimate was calculated by multiplying the time the agency expends to review product labeling (approximately 30 hours) by the hourly wage of a GS-12 employee in the locality pay area of Washington-Baltimore-Arlington in 2021 ($41.78).

15. Explanation for Program Changes or Adjustments*

The were no changes to the burden since the last renewal.

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.