U.S. Food and Drug Administration
Animal Food Labeling; Declaration of Certified and Non-Certified Color Additives

OMB Control No. 0910-0721

SUPPORTING STATEMENT **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 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 21 CFR 501.22(k) is consistent with the regulations requiring the declaration of color additives on human food labels. 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.

   We therefore request extension of OMB approval of the information collection provisions of the following citation:

   21 CFR 501.22(k) – Third-Party Disclosure

   Requires animal food manufacturers to declare on the animal food label the presence of certified and noncertified color additives in their animal food products.

2. Purpose and Use of the Information Collection

   As noted above, 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.

   Description of Respondents: Respondents to this collection of information are manufacturers of pet food products that contain color additives.

   Respondents are from the private sector (for-profit businesses).

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. Having become effective November

18, 2013, the agency estimates that the burden associated with the labeling requirements under 21 CFR 501.22(k) apply only to new product labels. 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

   FDA is the only agency that requires this information. The required information is not available from any other source.

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

   In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the *Federal Register* of February 20, 2018 (83 FR 7198). FDA received one comment.

   (Comment) One comment supported FDA's need for the information collection and characterized the burden of the information collection as low compared to the importance of informative food labels. The comment did not suggest revising our estimate of the burden. However, it suggested we should provide greater detail about how we estimated the number of respondents and the flow of new products.

   (Response) We based our estimate of the number of respondents on the number of pet food manufacturers subject to this regulation. The figure of 3,120 used in table 1 was derived from the number of establishments listed under North American Industrial Classification System (NAICS) codes 311111 and 311119, including very small

establishments. As noted in the 60-day notice, we based our estimate of the flow of new products on A.C. Nielsen data for the number of animal food product units for sale (for which sales of the products are greater than zero) in the latest year for which data is available, stated to be 25,874. Then, we assumed that the flow of new products would be 10 percent per year, for a figure of 2,587 new products per year. That figure was used in table 1 as our estimate of the total annual disclosures.

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 will be publicly disclosed on the label of animal foods. Information submitted to FDA under the food labeling regulations may contain trade secret and commercial confidential information. Only information that is releasable under the Agency's regulations in 21 CFR part 20 would be released to the public. This 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 collection of information does not contain questions 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 manufacturers of pet food products that contain color additives.

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

Table 1.--Estimated Annual Third-Party Disclosure Burden

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 additives or lake of color additive; labeling of color additives not subject to certification	3,120	0.8292	2,587	0.25 (15 minutes)	647

We estimate that the burden associated with the labeling requirements under § 501.22(k) applies only to new product labels. Because the vast majority of animal food products that

contain certified color additives are pet foods, we base our estimate of the number of respondents on the number of pet food manufacturers subject to this regulation. We estimate that there are approximately 3,120 manufacturers of pet food subject to either § 501.22(k)(1) or (k)(2), based on the number of establishments listed under North American Industrial Classification System (NAICS) codes 311111 and 311119, including very small establishments. We base our estimate of the flow of new products on A.C. Nielsen data for the number of animal food product units for sale (for which sales of the products are greater than zero) in the latest year for which data is available, stated to be 25,874. Then, we assumed that the flow of new products would be 10 percent per year, for a figure of 2,587 new products per year. This figure is used in table 1 as our estimate of the total annual disclosures. Assuming the approximately 2,587 new products are split equally among the 3,120 firms, then each firm would prepare labels for approximately 0.8292 new products per year (2,587 new products/3,120 firms is approximately 0.8292 labels per firm). We expect that firms prepare the required labeling for their products in a manner that takes into account at one time all information required to be disclosed on their product labels. Based on our experience with reviewing pet food labeling, we estimate that firms would require less than 0.25 hour (15 minutes) per product to comply with the requirement to include the color additive information pursuant to § 501.22(k). The total burden of this activity is 647 hours (2,587 labels × 0.25 hour/label is approximately 647 hours).

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Industrial Production Manager	647	$69.11	$44,714

[1] May 2017 National Industry-Specific Occupational Employment and Wage Estimates, Bureau of Labor Statistics and including 30% for benefits.

FDA estimates the cost of the information collection request to industry is $44,714 (rounded to nearest whole dollar). This figure was calculating the hourly wage rate for an industrial production manager by the total number of burden hours (647).

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

FDA estimates the cost to the Federal Government for this collection to be $1,172.10. 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 2018 ($39.07).

15. Explanation for Program Changes or Adjustments

The burden has not changed from the burden shown in the current inventory.

16. Plans for Tabulation and Publication and Project Time Schedule

This information 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.