Animal Food Labeling; Declaration of Certifiable Color Additives
OMB Control No. 0910-0721
Supporting Statement Part A

Justification

1. Circumstances Making the Collection of Information Necessary

The 1990 amendments to the Federal Food, Drug, and Cosmetic Act (the FD&C Act) amended section 403(i) to require 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." Section 210(f) of the FD&C Act defines "food" as any article used for food or drink for man or other animals, and thus the 1990 Amendments apply to both human and animal foods. Accordingly, the agency promulgated regulations regarding the declaration of color additives on human and animal food labels. FDA is therefore requesting to extend its approval for the information collection requirements set forth in 21 CFR section 501.22 detailing how certified color additives used in animal foods should be declared in the ingredient list and suggesting how noncertified color additives may be declared in the ingredient list.

2. Purpose and Use of the Information Collection

This information collection is associated with requirements under 21 CFR 501.22(k) in which animal food manufacturers must declare the presence of certified and noncertified color additives in their animal food products on the product label. Respondents to this collection are manufacturers of pet food that contain color additives who must disclose information on their product labeling.

3. Improved Information Technology and Burden Reduction

In the vast 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 or with questions concerning this Animal Food Labeling rule, about 90% will be by e-mail and 10% by mail.

4. Efforts to Identify Duplication and Use of Similar Information

This information is not otherwise collected and thus there duplication is unlikely.

5. Impact on Small Businesses or Other Small Entities

FDA believes that its requirements for the declaration of certifiable color additives in animal food labeling impose the minimal burden necessary; however, the regulations apply to all businesses alike.

6. Consequences of Collection the Information Less Frequently

This information is collected and updated only when a product label is changed. In the absence of the information the agency is not 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 the Federal Register of April 1, 2015 (80 FR 17445) FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received but did not respond to any of the four information collection topics solicited and is therefore not addressed by the Agency.

9. Explanation of Any Payment or Gift to Respondents

No payments or gifts are provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

This information will be publicly disclosed on the label of animal foods.

11. Justification for Sensitive Questions

This collection of information does not contain questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

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

Table 1. -- Estimated Annual Third-party Disclosure Burden[1]

21 CFR Section; Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Avg. 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	0.83	2,587	.25	647

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

Based on A.C. Nielsen Data, FDA estimates that the number of animal food product units subject to 21 CFR 501.22(k) for which sales of the products are greater than zero is 25,874. Assuming that the flow of new products is 10 percent per year, then 2,587 new animal food products subject to 21 CFR 501.22(k) will come on the market each year. FDA also estimates that there are about 3,120 manufacturers of pet food subject to either 21 CFR 501.22(k)(1) or (k)(2). Assuming the approximately 2,587 new products are split equally among the firms, then each firm would prepare labels for approximately 0.83 new products per year (2,587 new products/3,120 firms is approximately 0.83 labels per firm).

The agency expects 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, FDA estimates 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 21 CFR 501.22(k). The total burden of this activity is 647 hours (2,587 labels x 0.25 hour/label is approximately 647 hours).

12b. Annualized Cost Burden to Respondents

Type of Respondent	Total Burden Hours	Hourly Wage Rate[1]	Total Respondent Cost
Industrial Production Manager	647	$58.31	37,727

[1] Bureau of Labor Statistics 2014 Data

FDA estimates the cost of the information collection request to industry to be $37,727 (rounded to the nearest whole dollar). This figure was calculated by multiplying the hourly wage rate for an industrial production manager by the total number of burden hours (647).

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

There are no start-up or other costs associated with this collection of information.

14. Annualized Cost to the Federal Government

FDA estimates the cost to the Federal Government for this information collection to be $1,098. This estimate was calculated by multiplying the time the agency expends to review product labeling (approximately 30 hours) by the hourly wage for a GS-12 step 1 employee ($36.60).

15. Explanation for Program Changes or Burden Adjustments

Now that implementation of the final rule supporting this information collection has been realized, the agency has significantly lowered its burden estimate. We have also consolidated the two individual information collections into one. The result of these adjustments is a decrease in the annual number of responses to this collection by 12,871 with a corresponding decrease in hourly burden by 3,218 and cost decrease of $4,608,153.

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 is not seeking approval to exempt display of the expiration date for OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.