Animal Food Labeling; Declaration of Certifiable Color Additives
OMB # 0910-NEW
SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

The 1990 amendments amended section 403(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) 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." Because Section 210(f) of the FD&C Act defines "food" as any article used for food or drink for man or other animals, the 1990 Amendments apply to both human and animal foods. To comply with this statutory requirement, FDA amended its human food labeling regulations by adding a new paragraph to Section 101.22. However, the regulations pertaining to animal foods have not yet been promulgated.

The regulations pertaining to animal food labels are specified in Section 501.22. Pursuant to Section 501.22(a)(4), the term “artificial color” or “artificial coloring” means any color additive as defined in 21 CFR 70.3(f). Since the definition of color additives in Section 70.3(f) applies to color additives used in animal foods, the rationale for the changes in the food labeling regulations regarding certified color additives used in human foods, described in the proposed and final rules, 56 FR 28592 and 58 FR 2850, respectively, also apply to animal foods. Therefore, the changes FDA is proposing for animal food labels in Section 501.22 are the same as the ones made in Section 101.22 for human food labels. Specifically, this amendment adds a new paragraph to the animal food labeling regulations, 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 will be disclosed by animal feed manufacturers by display on the labels of animal feeds. The information is collected by the manufacturers for the benefit of the public such as purchasers of pet foods or owners of livestock. This is a new information collection based on the requirements of the 1990 amendments to the FD&C Act. Many feed manufacturers are already disclosing this information in accordance with the statutory requirements of the 1990 amendments.

3. Improved Information Technology and Burden Reduction

Firms are not required to submit labeling to FDA for review. In the vast majority of cases (>90%), animal feed companies revise their product labels without sending their draft labels to FDA for review. 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 duplicated anywhere else.

5. Impact on Small Businesses or Other Small Entities

FDA is adopting a 2-year effective date for the rule. As labels are normally revised within this time period, the burden to small businesses is minimized.

6. Consequences of Collection the Information Less Frequently

This information is collected and updated each time the label is changed. It cannot be collected less frequently.

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 proposed rule for public comment in the FEDERAL REGISTER of 11/23/2009 (74 FR 61074). FDA received 14 comments, all from consumers, which overwhelmingly supported the proposed rule. These comments approved the declaration of certified colors in animal food as an aid to consumers in avoiding food allergies and adverse reactions potentially caused by added colorings. Consumers value this additional information on the label in order to make informed choices about what their animals consume. There were only two comments that opposed the proposal and one comment that suggested additional requirements be adopted.

(Comment 1) Comment 1 described the proposed rule as “frivolous” and indicated that if the color additive was approved by FDA for inclusion in an animal food, the specific name of the color additive would not need to be declared. The commenter stated that without added colors the animal food would not be appealing. The comment concluded that adding information on certified colors would not benefit consumers.

(Response) The 1990 amendments required the declaration of certified colors on food labels and that requirement applies to animal food as well as human food. FDA is seeking to bring the declaration of certified colors in line with the labeling of human foods. Twelve of the comments indicated strong support from consumers for these proposed requirements and believed that such information on the label was valuable to them and would enable them to make informed decisions of their pet food choices.

(Comment 2) This comment expressed disapproval of the proposed rule claiming that the costs of the rule outweigh the benefits. The comment stated, “In difficult economic

times, it seems unwise to impose unknown costs on small businesses without concrete benefits to consumers." Additionally, the comment proposed exempting small businesses employing fewer that twenty employees from the labeling requirements of sections 501.22(k)(1) and (2), provided they state on the label "artificial color added."

(Response) First of all, in passing the 1990 amendments, Congress anticipated that declaration of certified colors, and nutrition labeling provisions in general, would impose some compliance costs for large and small businesses (58 FR 2070; 1993) (Food Labeling: Establishment of Date of Application). In the Color Additives proposed rule, in the Regulatory Flexibility Analysis (74 FR 61069) we considered the economic impact on small businesses as well as large firms, and tentatively concluded that at every establishment size, the expected cost of compliance would likely be significantly less than 1 percent of revenues for each label requiring new labeling. We had, therefore, tentatively determined that the compliance costs of the proposed rule are unlikely to have a significant economic impact on a substantial number of small entities and that compliance costs in general were reasonable.

Here FDA is decreasing the impact of such compliance costs by adopting a 2-year effective date to allow for depletion of animal food label inventories, and thus, FDA has done everything possible to both satisfy the statutory mandate and soften the impact on affected businesses.

The comment also indicated that the rule did not have "concrete benefits." However, the consumers that commented on the proposed rule overwhelmingly indicated their support of the rule, and their willingness to incur additional costs in order to have the benefit of more declared label information. One comment in support of the rule stated, "Many pet food manufacturers are already compliant with these new regulations because the FDA had provided informal education to manufacturers in the 1990s, in anticipation of the impending changes under [the 1990 amendments]." Therefore, FDA finds that from the comments received, the public generally supports the proposed rule as adopted.

(Comment 3) One comment, which supported the proposed rule, suggested that FDA go farther and require non-certified colors such as cochineal or carmine on animal food labels. The comment cited concerns regarding the potential for allergic reactions or illness caused by these color additives.

(Response) Congress mandated the declaration of certified colors in the 1990 amendments. Non-certified colors were not part of the Congressional initiative. However, CVM will work in concert with the Center for Food Safety and Applied Nutrition in evaluating whether additional authority in this area is needed.

FDA received no comments specifically directed at the Paperwork aspects of the rule.

9. Explanation of Any Payment or Gift to Respondents

There were no payments or gifts 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

There were no sensitive questions.

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 Reporting Burden[1]

21 CFR Section (or FDA Form #)	No. of Respondents	Number of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours	Total Capital Costs	
501.22 (k)(1)	2,250	6.67	15,000	0.25	3,750	$3,100,000[2]	
501.22 (k)(2)	2,250	0.2	450	0.25	112.5	$1,500,000	

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

[2] Because the range was $510,000 to $3.1 million, FDA has chosen to show the higher figure here.

The numbers for § 501.22(k)(1) in table 1 of the final rule (section III of this document) were taken from the Analysis of Impacts section of the final rule (section III of that document). The total number of establishments manufacturing dog, cat, and other non-production animal foods that could be subject to this final rule is estimated at 2,250. The annual frequency per response (6.67) is derived by dividing the 15,000 annual responses (i.e., labels) by the number of establishments (2,250). The total hours (3,750) is derived by multiplying the number of total annual responses (15,000) by 15 minutes (0.25) per response. Due to the proposed two year delay in the effective date of the final rule, the total capital costs range from $510,000 to $3.1 million, and operating and maintenance costs were estimated to be zero.

Final § 501.22(k)(2) states the appropriate terminology for the declaration of certification-exempt color additives on the ingredient list of labels of animal food. Although the suggested appropriate terminology for labels for declaration of colors exempt from certification is optional and offers some flexibility to a manufacturer in terms of how to

declare such color additives on its ingredient label, it is possible that some may voluntarily adopt the language specified in § 501.22(k)(2) when they are already relabeling their animal food products for other reasons such as for marketing purposes. The census data show up to 938 establishments produce animal feeds that may contain color additives exempt from certification. These additives may also be used at the 242 dog and cat food establishments in the United States, and any of the 1,303 non-employer establishments. We do not have data that can be used to estimate the number of product labels that will be voluntarily changed at the 2,250 establishments as a result of § 501.22(k)(2).

However, our analysis of the required changes for § 501.22(k)(1) estimated that about 6 percent of the products would require label changes after the 2-year effective date has passed (15 percent of labels that are currently out of compliance with proposed § 501.22(k)(1) times the 40 percent of those that would remain out of compliance after regular label changes occurring over 2 years). We assume that management would choose to make fewer voluntary label changes than required label changes. For our analysis, we assume that only one-half as much, or 3 years of these products, undergo voluntary label changes as in § 501.22(k)(2). This would result in 0.2 label changes per establishment for § 501.22(k)(2), or 450 label changes over the 2,250 establishments.

The hours per response for label review to determine compliance with the rule and the appropriate language to put on the label is estimated at 0.25 hours, which compares to the time allotted for animal food labels containing certified colors. The annual cost of label review is the hourly wage of an industrial production manager ($44.24) times 0.25 hours per response times the number of labels.

The upper-bound estimate of relabeling costs for the remaining labels (i.e., those reviewed for compliance with the proposed rule), is $3,350 per SKU. The total one-time cost of § 501.22(k)(2) would, therefore, be the cost of label review plus the cost of business practices, for an estimated total of approximately $1.5 million. The total hours spent, as shown in table 1 of this document, are 112.5 (450 times 0.25).

12b. Annualized Cost Burden to Respondents

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Industrial Production Manager (Reporting)	3862	$57.24 / hr[1]	$221,061

13. Capital Costs (Maintenance of Capital Costs)

The capital cost is the cost of label review and label changes to achieve compliance with § § 501.22(k)(1) and (k)(2). For § 501.22(k)(1), the cost of label changes is a range of 300 to 900 pet food stock keeping units (SKUs) times $1250 to $3550 per SKU equals $375,000 to 3.2 million. The cost of label review for § 501.22(k)(1) is $57.24 median hourly wage for an industrial production manager ($42.40 plus 35% for benefits) times .25

[1] May 2011 Occupational Employment and Wage Statistics, Bureau of Labor Statistics, NAICS 311100 Animal Food Manufacturing.

hours per response times the number of labels (15,000) equals $214,650. Over a 2 year transition period (discounted at 7 percent) for a total capital cost (label review and label changes) of approximately $500,000 to 3 million dollars.

Additionally, 0.38 label changes will occur per establishment for proposed § 501.22(k)(2), or 450 label changes over the 2,250 establishments. 450 labels times .25 hours for label review, times $57.24 median hourly wage (including benefits) for an industrial production manager equals $6,440 total cost for label review for § 501.22(k)(2).

For § 501.22(k)(2), the cost of label changes is $3,350 per SKU times 450 labels equals roughly $1,500,000. (See 74 FR 61071 for an in-depth economic explanation of these cost figures).

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14. Annualized Cost to the Federal Government

The cost to the Federal Government is 30 hours times $35.88 (the cost per hour for a GS-12 step 1 employee) equals $1,076.

15. Explanation for Program Changes or Burden Adjustments

This is a new information collection.

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

N/A

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification**.**