enforcement policy [6] published in the **Federal Register** in May 2001.

Since 2001, the agency has undertaken other fatigue mitigation efforts. Among these efforts was the Part 125/135 Aviation Rulemaking Committee (ARC),[7] which we convened in February 2003, to do a comprehensive regulatory review of 14 CFR parts 125 and 135. This review included rules on flight, duty, and rest. The ARC submitted its recommendations in September 2005. Also, in June 2008, we held an Aviation Fatigue Management Symposium [8] that provided the industry with the latest information on fatigue science, mitigation, and management. Currently, the agency is developing an Advisory Circular on fatigue that incorporates information from the Symposium. Additionally, in June 2009, the FAA chartered the Flight and Duty Time Limitations and Rest Requirements ARC [9] comprised of labor, industry, and FAA representatives to develop recommendations for an FAA rule based on current fatigue science and a thorough review of international approaches to the issue.

Reason for Withdrawal

The FAA is withdrawing the 1995 Flight Crewmember Duty Period Limitations, Flight Time Limitations and Rest Requirements NPRM because it is outdated and because it raised many significant issues that the agency needed to consider before proceeding with a final rule. Instead of adopting the provisions of the 1995 NPRM, the FAA intends to develop a new NPRM later this year that considers the Flight and Duty Time Limitations and Rest Requirements ARC recommendations, scientific research, NTSB recommendations on fatigue and flight duty time, and the recommendations of the Part 125/135 ARC.

Conclusion

The FAA is withdrawing the December 1995 NPRM for the reasons stated in this notice and will issue a new proposed rule to address flight, duty, and rest. We will provide the opportunity for comment on the new rulemaking through the NPRM process.

[6] 66 FR 27548; May 17, 2001.

[7] 68 FR 5488; February 3, 2003 (*See also* 67 FR 42323; July 17, 2003).

[8] *See www.faa.gov/about/office%5Forg/headquarters%5Foffices/avs/offices/afs/afs200/* for the Symposium proceedings.

[9] See *http://www.faa.gov/about/office%5Forg/headquarters%5Foffices/avs/offices/afs/afs200/* for the ARC Charter.

Issued in Washington, DC, on November 17, 2009.

Chester D. Dalbey,

Deputy Director, Flight Standards Service.

[FR Doc. E9–28054 Filed 11–20–09; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 501

[Docket No. FDA–2009–N–0025]

RIN 0910–AG02

Animal Food Labeling; Declaration of Certifiable Color Additives

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations regarding the declaration of certified color additives on the labels of animal food including animal feeds and pet foods. FDA is proposing this amendment in response to the Nutrition Labeling and Education Act of 1990 (the 1990 amendments), which amended the Federal Food, Drug, and Cosmetic Act (the act) by requiring, among other things, the listing on food labels of the common or usual names of all color additives required to be certified by FDA. An additional purpose of this amendment is to make these regulations consistent with the regulations regarding the declaration of certified color additives on the labels of human food. The proposed rule also suggests appropriate terminology for the declaration of certification-exempt color additives on the labels of animal food.

DATES: Submit written or electronic comments on the proposed rule by February 22, 2010. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by December 23, 2009, (see the ''Paperwork Reduction Act of 1995'' section of this document).

ADDRESSES: You may submit comments, identified by Docket No. FDA–2009–N–0025 and/or RIN number 0910–AG02, by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Regulatory Affairs, Office of Management and Budget (OMB) (see the ''Paperwork Reduction Act of 1995'' section of this document).

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

Instructions: All submissions received must include the agency name and Docket No(s). and Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov*, including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number(s), found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: John P. Machado, Center for Veterinary Medicine (HFV–228), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–453–6854; e-mail: *john.machado@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Before passage of the 1990 amendments, the act provided that colorings could be declared collectively on food product labels using the term ''colorings.'' However, the 1990 amendments amended section 403(i) of the act (21 U.S.C. 343(i)) to require that certified color additives be declared by their common or usual names and not be designated by the term ''colorings.'' As a result of this change in the statute, each certified color additive (e.g., FD&C

Blue No. 2, FD&C Red No. 40) used in or on a food must be declared on labeling by its common or usual name, but color additives exempt from certification (e.g., caramel, paprika, and beet juice) may still be declared collectively.

In response to this statutory requirement, FDA issued a final rule on January 6, 1993 (58 FR 2850), which was codified in title 21 of the Code of Federal Regulations, § 101.22 (21 CFR 101.22). Specifically, § 101.22(k) details how color additives used in human foods are to be declared in the ingredient list. The agency also permitted the use of abbreviated names (e.g., Blue 2, Red 40) for certified color additives.

Although the 1990 amendments apply both to human and animal foods, the regulations pertaining to animal foods have not yet been issued. Nonetheless, the provisions of the 1990 amendments that amend section 403(i) of the act are self-executing and apply to animal food labels even in the absence of issued regulations under this authority. Because FDA has not published regulations applicable to animal food under the 1990 amendments, FDA has generally exercised enforcement discretion with regard to the requirements of this provision of the act as they pertain to animal food labels. Because of this exercise of enforcement discretion, as well as the decision to provide an opportunity to deplete the current stock of animal food labels prior to enforcing the requirements with regard to animal food products, a final rule issued based on this proposed rule would have a 2-year effective date.

This proposed rule adds a paragraph to § 501.22 (21 CFR 501.22), detailing how certified color additives used in or on animal foods must be declared in the ingredient list. In addition, the proposed rule sets out different ways a manufacturer can comply with the requirement that color additives not subject to certification under the act be declared collectively on the label.

II. Description of the Proposed Rule

The 1990 amendments amended section 403(i) of the act to require that certified color additives used in or on a food be declared by their common or usual names. Because section 201(f) of the act (21 U.S.C. 321(f)) defines ''food'' as any article used for food or drink for man or other animals, the changes made to section 403(i) by the 1990 amendments apply to both human and animal foods. In response to this new statutory amendment, FDA revised its human food labeling regulations by adding paragraph (k) to § 101.22. These regulations were published in the **Federal Register** on June 21, 1991 (56 FR 28592) (proposed rule) and January 6, 1993 (final rule). However, the regulations pertaining to animal foods have not yet been issued.

The changes FDA is proposing for animal food labels are similar to the ones made in § 101.22 for human food labels. Specifically, this proposed regulation adds paragraph (k) to the animal food labeling regulations at § 501.22, detailing how certified color additives used in animal foods must be declared in the ingredient list, and sets out the various ways that manufacturers may collectively declare certified-exempt color additives in the ingredient list.

New § 501.22(k) proposes that a color additive or the lake of a color additive subject to certification under section 721(c) of the act (21 U.S.C. 379(c)) shall be declared by the common or usual name of the color additive as listed in the applicable regulation in part 74 (21 CFR part 74) or part 82 (21 CFR part 82), except that it is not necessary to include the ''FD&C'' prefix or the term ''No.'' in the declaration. However, the term ''Lake'' shall be included in the declaration for the lake of a certified color additive (e.g., Blue 1 Lake). Manufacturers may parenthetically declare an appropriate alternative name of the certified color additive following its common or usual name as specified in part 74 or part 82. The new provision also provides a number of options for collectively declaring the presence in food of the certified-exempt color additives that are listed in part 73 (21 CFR part 73). Color additives not subject to certification may be declared as ''Artificial Color,'' ''Artificial Color Added,'' or ''Color Added'' (or by an equally informative term that makes clear that a color additive has been used in the food). Alternatively, such color additives may be declared as ''Colored with _____'' or ''_____ color,'' the blank to be filled with the name of the color additive listed in the applicable regulation in part 73.

III. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). In accordance with Executive Order 12866, FDA has carefully analyzed the economic effects of this proposal and has determined that the final rule, if issued, will not be a significant regulatory action as defined by the Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. As discussed more fully in section IV of this document, we have prepared an initial regulatory flexibility analysis. Our initial analysis indicates 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 have, therefore, determined that the compliance costs of the proposed rule are unlikely to have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $133 million, using the most current (2008) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

A. Purpose of Rule

This proposed rule would require that the common or usual name of all color additives that are required to be certified by FDA be listed on the label of animal foods. This change would amend FDA's animal food regulations to include certain requirements of the 1990 amendments, as was previously done with the human food regulations. Additionally, the proposed rule suggests how color additives not certified by FDA should be declared on the ingredient list of animal foods. As stated previously in this document, the 1990 amendments require that all food labels list the common or usual names of all color additives that are required to be certified by FDA. Therefore, the agency lacks a great deal of flexibility in the development of this rule.

B. Benefits

The principal benefit of this rule is that it would provide additional consumer information for purchasers of pet food and other animal food products to consider in making their buying decisions for those animal food products that are not currently labeled in accordance with the provisions of this proposed rule. The agency does not have any data with which to quantify the extent to which having this additional information would result in more informed buying decisions by consumers. The rule also would provide some voluntary options for all animal food manufacturers, including options for terminology they can use when declaring certification-exempt color additives on their product labels.

C. Costs

The rule proposes that the effectiveness date be 2 years from the date of publication of the final rule. This time is intended to allow animal food manufacturers some time to deplete their current label inventories as they make the transition to the new label. We do not consider this proposal to require a major label redesign because it would likely only necessitate minor changes in wording on the ingredient list. Many animal food manufacturers are already declaring certified color additives in their labeling by their common or usual name.

The rule would impose some review costs on those animal food manufacturers that use or intend to use certified color additives. Because the vast majority of animal food products that contain certified color additives are pet foods, we limit the costs to review labels for the use of certified color additives to pet food manufacturers. Each of these manufacturers would need to review the labels of its pet food products to determine the current level of compliance with the proposed rule. Those manufacturers determined not to be in compliance with the proposed rule would incur additional costs under § 501.22(k)(1) to change the wording of their labels.

Animal feeds for a limited number of production animals, such as animal feeds for certain farm-raised fish and poultry, also contain color additives. However, we believe the color additives used in animal feeds for fish and poultry are generally certification-exempt, because such color additives can produce the desired colors in edible tissues of these animals more efficiently than certified color additives; currently, no certified color additive is approved to alter the color of the edible tissue of these animals. We invite public comment and data on the use of color additives in animal feeds for production animals in general, and in particular, on the use of certified color additives in fish and poultry feeds.

Animal food manufacturers using certification-exempt color additives in their products would only incur additional relabeling costs under § 501.22(k)(2) if they were to revise their labels to use one of the specific terminology options set forth in that provision. Although § 501.22(k)(2) lists specific terms that manufacturers can use when declaring color additives that are exempt from certification (e.g., ''Artificial Color'' or ''Color Added''), the provision also would permit such color additives to be declared using other equally informative terms that make clear that a color additive has been used in the food. FDA believes that most manufacturers of animal food products containing certification-exempt color additives are already declaring the presence of these ingredients in a manner that complies with proposed § 501.22(k)(2). We are not aware of any private incentives that would lead these manufacturers to voluntarily change their labels solely for the purpose of adopting one of the terms identified in proposed § 501.22(k)(2), although it is conceivable that some may make such a change as part of a larger effort to change their labels for other reasons, such as to comply with § 501.22(k)(1) or as part of scheduled labeling changes. Because use of the terminology specified in proposed § 501.22(k)(2) is optional and the presence of certification-exempt color additives can instead be declared in other equally informative ways, we do not expect proposed § 501.22(k)(2) to impose any new compliance costs on animal food manufacturers.

Pet food labeling costs

We do not have data sources that can be used to precisely estimate the number of pet food products. For the purpose of this analysis we assume, based on an industry source, that there are approximately 15,000 different brands of pet foods.[1] Further, we lack extensive data on pet food labels to confidently estimate the number of such labels that are currently consistent with the provisions of the proposed rule. An informal survey of pet food products for dogs, cats, rabbits and guinea pigs, however, found that only 13 of the 68 products surveyed had labels that listed color ingredients in a manner that might be determined not to be in compliance in the event the proposed rule becomes final.[2] Only 1 of the 13 products would definitely be considered out of compliance with the rule, and that was due to its failure to individually identify which of the identified certified color additives were the colors requiring certification and which were the lakes colors requiring certification.

On many of the other 12 product labels, the phrase ''and other color(s)'' or similar language followed immediately after a list of FDC colors requiring certification. In these cases, we believe it is likely that the phrase is being used to designate colors that do not require certification. However, because we could not rule out the possibility that the phrase ''and other color(s)'' or a similar phrase was being used to declare colors requiring certification that therefore would need to be listed individually by their common or usual name, we included them in the group of pet food product labels that would possibly be out of compliance. Based on the previous reasoning, we project the midpoint of the 12 possible cases of noncompliance represent actual cases of noncompliance with the proposed rule. Therefore, we project an upper end of the estimated noncompliance range at 7 of the 68 cases in the sample (6 of the possibly noncompliant cases plus the 1 case that is almost certainly out of compliance), or about 10 percent.

Due to the uncertainty surrounding pet food products in other market niches as well as those that are imported (all or almost all of those in the informal sample are products that were produced in the United States, although some ingredients may have been imported), it may be proper to account for these products by increasing the possible non-compliance level. However, because of the arguments mentioned previously concerning our likely overestimation of the upper range of our estimate in our informal survey, we have only increased our high-end estimate of products that would not be in compliance with the proposed rule to 15 percent. Although only 1.5 percent of the sample would definitely be out of compliance, to account for some uncertainty we have increased the low end of our compliance range to 5 percent. We estimate current product labeling that would not be in compliance with the proposed rule to range from 750 to 2,250

[1] Veterinary News Network, *http://www.myvnn.com*, accessed May 21, 2007. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

[2] Informal survey of pet foods brands taken on April 20, 2007 at one grocery store and one drug store in Anne Arundel County, MD by FDA personnel.

products, or 5 to 15 percent of the estimated 15,000 different brands of pet food products. We request comment and additional data on the number of existing pet food product labels that would need to be modified if this proposed rule becomes final.

We have estimated a cost for the combined effort by pet food industry management to become familiar with the requirements of the rule, plus the effort to determine the compliance status of each of the approximately 15,000 products. We project that, on average, the compliance status of each product could be determined within 15 minutes by an industry compliance officer. In some instances, notably those involving companies with fewer products, the average may be longer due to the additional time spent on general education and awareness of the rule's requirements being apportioned over fewer products. For those companies with tens or hundreds of product labels, however, the average time to review an individual pet food ingredient label could easily be less than our estimate of 15 minutes per label. In any case, at 15 minutes per label, the one-time effort to review the 15,000 labels would amount to 3,750 hours. Using the median wage rate of $32.77 per hour for an industrial production manager (adding 35 percent to account for benefits results in a cost of $44.24 per hour), the cost of this label review would amount to about $166,000.[3]

FDA's Labeling Cost Model presents low, medium, and high cost estimates for all aspects of the label manufacturing process, from the administrative efforts through physical creation of the label, as well as an estimate for the loss of current label inventory[4]. We do not have specific data on the frequency of scheduled label changes for the pet food industry, but believe it would be similar to the human food industry. The model also includes a field that attempts to show to what extent human food labeling changes can be coordinated with scheduled labeling changes based on the time period within which the additional changes must be made. The model suggests parameters that lead to cost estimates that fall exponentially with the time allowed for labeling changes. The default or suggested percentages in the human foods model for a 2-year effectiveness date are 33 percent for private label products and 67 percent for brand name products. For pet foods, we believe the large majority of products are branded, implying that our estimate of all pet food labels that would have a scheduled label change within the 2-year effectiveness date should be closer to 67 percent than 33 percent (the Labeling Cost Model does not include data for products made by the pet food industry). Further, the general conclusion of a discussion with an industry association was that 1.5 to 2 years is a reasonable estimate for the life of a pet food label order, and for large manufacturers it is likely less than 1 year.[5] Based on these insights and lacking any other data source, we estimate that 60 percent of the pet food ingredient labeling changes could be coordinated with scheduled labeling changes. We invite public comment and data on the extent to which pet food ingredient labeling changes can be coordinated with scheduled labeling changes. (See the **COMMENTS** section of this document.)

We ran the model with several different human food items as proxies for pet foods, including canned seafood, cereal, flour meal, and bagged snack food, assuming a 2-year effectiveness date for the rule. The resulting total costs (which include label inventory loss) per stockkeeping unit (SKU) varied from low cost estimates for all but the canned seafood around $800, and with high cost estimates for canned seafood approaching $4,750. For the purpose of this analysis, we propose to use the median cost estimates from the cereal and canned seafood model results, or a range from about $1,250 per SKU to about $3,550 per SKU.

We project that only 300 to 900 pet food SKUs would be required to undertake an earlier labeling change as a result of this rule. This represents the 40 percent of SKUs that would not be able to coordinate the label change required by this rule with regularly scheduled label changes multiplied by the 750 to 2,250 SKUs that are not expected to be in compliance with the rule. Based on the range of per SKU costs described previously, the additional one-time labeling costs (including inventory loss) would range from $375,000 to about $3.2 million. Discounting these costs until the end of the 2-year transition period (at a 7-percent discount rate) results in one-time costs of about $328,000 to $2.8 million (at a 3-percent rate, the one-time cost would range from $353,000 to $3.0 million).

We estimate total pet food industry one-time costs (discounted at 7 percent) to range from about $500,000 to $3 million, including both the effort to determine compliance with the proposed rule and the labeling costs for those SKUs that would remain out of compliance after 2 years from the date of publication of the final rule. We do not project any additional annual reporting costs.

Analysis of Alternatives

Because section 403(i) of the act as amended by the 1990 amendments specifically requires certified color additives used in food to be declared by their common or usual names, we lacked the flexibility to consider other ways to declare certified color additives on the labels of animal food products. Based on the 2-year effectiveness date included in this proposal, total discounted one-time compliance costs would range from about $500,000 to $3 million. As indicated earlier, the 2-year effective date is to allow for an orderly transition from current label inventory without a significant, additional cost to the animal food products industry. FDA seeks comment on this issue.

IV. Regulatory Flexibility Analysis

The Regulatory Flexibility Act requires agencies to prepare a regulatory flexibility analysis if a rule is expected to have a significant economic impact on a substantial number of small entities. Although we believe it is unlikely that significant economic impacts would occur, we cannot rule out the possibility completely because of uncertainty in the distribution of the affected products among establishments producing animal food products. The following constitutes the initial regulatory flexibility analysis.

One requirement of the Regulatory Flexibility Act is a succinct statement of any objectives of the rule. As stated previously in this analysis, the agency intends to amend the ingredient labeling regulations for animal feeds and pet foods to require that the common or usual name of all color additives that are required to be certified by FDA be listed on the label. This change would codify in FDA's animal food labeling regulations the requirements of the 1990 amendments, as was previously done for the food product labels for humans.

The Regulatory Flexibility Act also requires a description of the small entities that would be affected by the rule, and an estimate of the number of small entities to which the rule would apply. Dog and cat food manufacturers are classified in the North American

[3] U.S. Department of Labor, Bureau of Labor Statistics, Occupational Employment Statistics NAICS 311100—Animal Food Manufacturing (*http://www.bls.gov/oes/current/naics4_311100.htm*).

[4] *http://www.foodrisk.org/lcm.htm.* (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

[5] E-mail communication between industry association and FDA personnel on March 8, 2007.

Industrial Classification System (NAICS) under industry code 311111—Dog and Cat Food Manufacturing. Census data from 2002 in this category shows that 175 companies with 242 establishments make dog and cat foods in the United States.

NAICS industry code 311119 is identified as Other Animal Food Manufacturing. The 2002 census data for this category reported a total of 1,042 companies with 1,567 establishments. At least 629 of these establishments, however, prepared feeds for beef cattle, dairy cattle, swine, poultry (other than chickens and turkeys) and other minor production animal species. These establishments manufacture animal feed for production animals such as cattle and swine that ordinarily would not include any color additives in their products. This reduces the number of establishments in industry code 311119 that are subject to § 501.22(k)(1) to 938.

We have not reduced the number of establishments any further to account for the 350 establishments that manufacture feed or feed ingredients for chickens and turkeys, fish species and other minor species, which are the types of products that we believe are more likely to contain a color additive to aid in their marketability. Based on our understanding that feed or feed ingredients for chickens and turkeys, fish, and some other minor species typically do not contain color additives requiring certification, we believe that manufacturers of these products would only be minimally affected by proposed § 501.22(k)(1), if at all. However, because we cannot rule out the possibility that they would, at some point in the future, use a color additive requiring certification, we do not exclude them from the total of 938 establishments. Thus, using the 2002 census data, we estimate that the total number of establishments manufacturing dog, cat, and production animal foods that could be affected by § 501.22(k)(1) may be as large as 1,180 establishments (242 + 938).

The Small Business Administration defines businesses in NAICS categories 311111 and 311119 as small entities if they employ less than 500 employees. Census data shows that only 1 establishment with NAICS code 311111 employs 500 or more employees and that no establishments within NAICS code 311119 employ 500 or more employees. The existence of some multi-establishment companies in each NAICS classification would likely increase the number of companies that would not meet the definition of a small entity because companies comprised of more than one establishment are likely to have more employees. Nonetheless, we would expect that a large number of the 1,180 establishments that manufacture dog food, cat food, or other animal food that might contain a color additive requiring certification would meet the criteria to be considered small businesses.

Census data on industry shipments for dog and cat food manufacturers is not available for establishments with one to four employees in 2002. For those establishments with 5 to 9 employees, and those with 10 to 19 employees, the average annual value of shipments ranges from $3.37 to $4.16 million. For all establishments with 20 or more employees, it is much greater. If a manufacturer composed of only one establishment of five to nine employees had to undertake one product relabeling due to this rule, the one-time cost of this effort would represent only about 0.11 percent of average annual revenues. Those establishments with 10 to 19 employees could have 11 SKUs needing relabeling before their one-time costs equal 1 percent of average annual revenues, while establishments with 20 or more employees could have more than 50 SKUs needing relabeling before their one-time costs equal 1 percent of average annual revenues.

For those establishments with one to four employees that manufacture other animal foods, the average annual value of shipments is about $950,000. The average value of shipments for establishments in this industry with five or more employees is greater than $3.8 million. An average company composed of one establishment with one to four employees would expend 0.37 percent of its revenues for the cost of relabeling one SKU as a result of this rule. Establishments with 5 to 9 employees and those with 10 to 19 employees could have 11 and 24 SKUs requiring relabeling after 2 years, respectively, before their one-time costs would account for 1 percent of average annual revenues. All larger establishments could have 100 or more SKUs requiring relabeling after 2 years before their one-time costs would account for 1 percent of average annual revenues.

Although the data show that the cost for relabeling one SKU would not likely represent a significant burden on a substantial number of small companies, we do not have data on either the number of affected animal food products manufactured by establishments or firms of any size, or the distribution of those animal food products that would not have met the requirements of the rule within 2 years of the publication of the final rule. That being the case, we must allow for the possibility, however unlikely, that the rule could have a significant impact on a substantial number of small firms.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The analysis above shows that at every establishment size, the expected cost of compliance would be significantly less than 1 percent of revenues for each SKU requiring new labeling. The estimated number of SKUs requiring new labeling makes it unlikely that their distribution among establishments would result in any establishment incurring compliance costs greater than 1 percent of revenues. The agency believes, therefore, that this proposed rule would be unlikely to have a significant economic impact on a substantial number of small entities. FDA requests comment on this issue.

V. Environmental Impact

The agency has determined that establishment of this labeling requirement would not increase the existing levels of use or change the intended uses of color additives or their substitutes. Therefore, under 21 CFR 25.30(k), this proposed rule is determined to be categorically excluded from the need to prepare an environmental assessment or an environmental impact statement.

VI. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires agencies to ''construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State law conflicts with the exercise of Federal authority under the Federal statute.'' Federal law includes an express preemption provision that preempts ''any requirement for the labeling of food of the type required by * * * [21 U.S.C. 343(i)(2)] * * * that is not identical to the requirements of such section * * *'' 21 U.S.C. 343–1(a)(2). This proposed rule, if made final, would create requirements for declaring the presence of certified color additives on the labels of animal food, including animal feeds and pet foods under 21 U.S.C. 343(i)(2).

VII. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB), under

the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). A description of these provisions is given in table 1 of this document with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques and other forms of information technology.

Title: Animal Food Labeling; Declaration of Certifiable Color Additives.

Description: FDA is proposing this amendment in response to the 1990 amendments, which amended the act by requiring, among other things, the listing on food labels of the common or usual names of all color additives required to be certified by FDA. An additional purpose of this amendment is to make these regulations consistent with the regulations regarding the declaration of certified color additives on the labels of human food. The proposed rule also suggests appropriate terminology for the declaration of certified-exempt color additives on the labels of animal food.

Description of Respondents: Animal feed industry, which also includes those establishments manufacturing pet foods.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Capital Costs	
501.22 (k)(1)	1,180	12.71	15,000	.25	3,750	$3,000,0002[2]	
501.22(k)(2)	1,180	12.71	450	.25	112.5	$1.5,000,000	

[1]There are no operating and maintenance costs associated with this collection of information.
[2]Because the range was $500,000 to $3 million, FDA has chosen to show the high figure here.

The numbers for § 501.22(k)(1) in table 1 of this document were taken from section III of this document. As discussed in section IV of this document, the total number of establishments manufacturing dog, cat, and other non-production animal foods is estimated at 1,180. The annual frequency per response (12.71) is derived by dividing the 15,000 annual responses (i.e., labels) by the number of establishments (1,180). The total hours (3,750) is derived by multiplying the number of total annual responses (15,000) by 15 minutes (.25) per response. Due to the proposed 2-year delay in the effective date of the final rule, the total capital costs range from $500,000 to $3 million, and operating and maintenance costs were estimated to be zero.

New § 501.22(k)(2) proposes appropriate terminology for the declaration of certification-exempt color additives on the ingredient list of labels of animal food. Color additives not subject to certification may be declared as ''Artificial Color,'' ''Artificial Color Added,'' or ''Color Added'' (or by an equally informative term that makes clear that a color additive has been used in the food). Alternatively, such color additives may be declared as ''Colored with _____'' or '' _____ color,'' the blank to be filled with the name of the color additive listed in the applicable regulation in part 73 of this chapter. 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 shows that 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. We do not have data that can be used to estimate the number of product labels that will be voluntarily changed at the 1,180 establishments as a result of proposed § 501.22(k)(2). However, our analysis of the required changes for proposed § 501.22(k)(1) estimated that about 6 percent of the products would require label changes after the 2-year effectiveness date has passed (15 percent of labels that are currently out of compliance with proposed § 501.22(k)(1) times the 40 percent of these 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 percent of these products, undergo voluntary label changes as proposed in § 501.22(k)(2). This would result in 0.38 label changes per establishment for proposed § 501.22(k)(2), or 450 label changes over the 1,180 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 .25 hour, 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 .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 changing 450 labels as part of normal business practices, for an estimated total of about $1.5 million. The total hours spent, as shown in Table 1 of this document, are 112.5 (450 times .25).

The information collection provisions of this proposed rule have been submitted to OMB for review. Interested persons are requested to fax comments regarding information collection to the Office of Information and Regulatory Affairs, OMB (see the **DATES** section of this document). To ensure that comments on information collection are received, OMB recommends that written

comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974.

VIII. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 501

Animal food labeling, Specific animal food labeling requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 501 be amended as follows:

PART 501—ANIMAL FOOD LABELING

1. The authority citation for 21 CFR part 501 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371.

2. Section 501.22 is amended by adding paragraph (k) to read as follows:

§ 501.22 Animal foods; labeling of spices, flavorings, colorings, and chemical preservatives.

* * * * *

(k) The label of an animal food to which any coloring has been added shall declare the coloring in the statement of ingredients in the manner specified in paragraphs (k)(1) and (k)(2) of this section.

(1) A color additive or the lake of a color additive subject to certification under section 721(c) of the act shall be declared by the name of the color additive listed in the applicable regulation in part 74 or part 82 of this chapter, except that it is not necessary to include the ''FD&C'' prefix or the term ''No.'' in the declaration, but the term ''Lake'' shall be included in the declaration of the lake of the certified color additive (e.g., Blue 1 Lake). Manufacturers may parenthetically declare an appropriate alternative name of the certified color additive following its common or usual name as specified in part 74 or part 82 of this chapter.

(2) Color additives not subject to certification may be declared as ''Artificial Color,'' ''Artificial Color Added,'' or ''Color Added'' (or by an equally informative term that makes clear that a color additive has been used in the food). Alternatively, such color additives may be declared as ''Colored with_____'' or ''_____ color,'' the blank to be filled with the name of the color additive listed in the applicable regulation in part 73 of this chapter.

Dated: November 17, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–27984 Filed 11–20–09; 8:45 am]

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PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 4041

Purchase of Irrevocable Commitments Prior to Standard Termination

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Request for public comment.

SUMMARY: Practitioners and employers have requested guidance from PBGC on the extent to which plan administrators may purchase irrevocable commitments to provide plan benefits before initiating a standard termination under section 4041(b) of ERISA. PBGC is soliciting public comments to help develop this guidance. The issues on which PBGC seeks comments include the extent to which such purchases of irrevocable commitments violate statutory and regulatory termination requirements, safeguards for participants and beneficiaries, and sanctions for violations.

DATES: Comments must be received on or before January 22, 2010.

ADDRESSES: Comments may be submitted by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the Web site instructions for submitting comments.
- *E-mail: reg.comments@pbgc.gov.*
- *Fax:* 202–326–4224.
- *Mail or Hand Delivery:* Legislative and Regulatory Department, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005–4026.

Comments received, including personal information provided, will be posted to *http://www.pbgc.gov.* Copies of comments may also be obtained by writing to Disclosure Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005–4026 or calling 202–326–4040 during normal business hours. (TTY and TDD users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4040.)

FOR FURTHER INFORMATION CONTACT: Constance Markakis or Catherine B. Klion, Attorneys, Legislative and Regulatory Department, Pension Benefit Guaranty Corporation, Suite 12300, 1200 K Street, NW., Washington, DC 20005–4026, 202–326–4024. (For TTY–TTD users, call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4024.)

SUPPLEMENTARY INFORMATION: PBGC administers the termination insurance program under Title IV of the Employee Retirement Income Security Act of 1974 (ERISA). Under section 4041(b) of ERISA, a plan that has sufficient assets to pay all plan liabilities may terminate in a standard termination. Standard termination requirements (including reporting and disclosure requirements and restrictions on distributing plan assets during the termination process) are set forth in the statute, PBGC's regulation on Termination of Single Employer Plans, 29 CFR part 4041, and termination forms and instructions, available on PBGC's Web site, *http://www.pbgc.gov.*

Questions have been raised as to the extent to which a plan administrator may purchase irrevocable commitments for some or all participants during a period of time before initiating a standard termination. Plans sometimes consider purchase of an irrevocable commitment (an obligation by an insurer to pay benefits) to take advantage of favorable interest rates, or to gradually prepare for a termination.

Although PBGC understands these considerations, PBGC has concerns about whether such purchases could circumvent the statutory and regulatory protections afforded participants and beneficiaries under the standard termination process. PBGC has provided only limited informal guidance on this issue.[1] This notice seeks public comment to help develop more comprehensive guidance.

Standard Termination Process

Under part 4041, a single-employer plan may terminate in a standard termination if, in accordance with regulatory requirements, the plan

[1] 2009 Blue Book Q&A 8, available on PBGC's Web site, *http://www.pbgc.gov.* Blue Books are summaries of the questions and answers discussed at meetings between PBGC staff and representatives of the Enrolled Actuaries Program Committee in preparation for the annual Enrolled Actuaries Meetings. The summaries reflect the views of individual staff members and do not represent the official position of PBGC.