4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0025]

Agency Information Collection Activities; Proposed Collection; Comment Request; Animal Food Labeling; Declaration of Certifiable Color Additives

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on burden hours associated with the animal food industry declaring the presence of certified and noncertified color additives in their animal food products on the animal food label.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to http://www.regulations.gov. Submit written comments on the collection of information to the

Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following 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, when appropriate, and other forms of information technology.

Animal Food Labeling; Declaration of Certifiable Color Additives--21 CFR 501.22(k) (OMB Control Number 0910-0721--Extension)

This information collection is associated with requirements under § 501.22(k) (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. The Agency issued this regulation in response to the Nutrition Labeling and Education Act of 1990 to make animal food regulations consistent with the regulations regarding the declaration of color additives on human food labels and to provide animal owners with information on the colors used in animal food.

Respondents to this collection are manufacturers of pet food that contain color additives. Manufacturers of certain food or food ingredients do not have products that contain color additives requiring certification (e.g., food for chickens, fish, and some other species, including some pet foods) and would thus be minimally affected by § 501.22(k)(1). However, since we cannot rule out the possibility that they may at some point use a color additive requiring certification, we have consolidated the burden estimates for § 501.22(k)(1) and (k)(2). Additionally, we believe that this burden is more accurately characterized as a third-party disclosure burden because FDA does not require routine submission of pet food labeling to the Agency.

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	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	0.83	2,587	0.25	647

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

Because § 501.22(k) became effective November 18, 2013, the Agency estimates 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 limit our burden estimate to reviewing labels for the use of certified color additives to pet food manufacturers subject to this regulation.

Based on A.C. Nielsen Data, FDA estimates that the number of animal food product units subject to § 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 § 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 § 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 under § 501.22(k). The total burden of this activity is 647 hours (2,587 labels x 0.25 hour/label is approximately 647 hours).

Dated: March 25, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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