4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [**INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**].

ADDRESSES: To ensure that comments on the 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: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0721. Also include the FDA 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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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 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 (Pub. L. 101-535) 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 501.22(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.

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.

FDA estimates the burden of 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	.25 (15 minutes)	647

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

Having become effective November 18, 2013, the Agency estimates that the burden associated with the labeling requirements under § 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.

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 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).

Dated: June 25, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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