

FSMA focuses on ensuring the safety of the U.S. food supply by shifting the efforts of Federal regulators from response to prevention and recognizes the importance of strengthening existing collaboration among all stakeholders to achieve common public health and security goals. FSMA identifies some key priorities for working with partners in areas such as reliance on Federal, State, and local agencies for inspections; improving foodborne illness surveillance; and leveraging and enhancing State and local food safety and defense capacities. Section 108 of FSMA (NAFDS) requires the U.S. Department of Health and Human Services (HHS) and the U.S. Department of Agriculture (USDA), in coordination with the Department of Homeland Security (DHS), to work together with State, local, territorial, and tribal governments to monitor and measure progress in food defense.

In 2015, the initial NAFDS Report to Congress detailed the specific Federal response to food and agriculture defense goals, objectives, key initiatives, and activities that HHS, USDA, DHS, and other stakeholders planned to accomplish to meet the objectives outlined in FSMA. The NAFDS charts a direction for how the Federal Agencies,

in cooperation with State, local, territorial, and tribal governments and private sector partners, protect the nation's food supply against intentional contamination. Not later than 4 years after the initial NAFDS Report to Congress (2015), and every 4 years thereafter (*i.e.*, 2019, 2023, 2017, etc.), HHS, USDA, and DHS are required to revise and submit an updated report to the relevant committees of Congress.

HHS/FDA is primarily responsible for obtaining the information from Federal and State, local, territorial, and tribal partners to complete the NAFDS Report to Congress. An interagency working group will conduct the survey and collect and update the NAFDS as directed by FSMA, including developing metrics and measuring progress for the evaluation process.

The proposed survey of Federal and State partners will be used to determine what food defense activities, if any, Federal and/or State Agencies have completed (or are planning) from 2015 to 2019. Planning for the local, territorial, and tribal information collections will commence after the collection and reporting of Federal and State Agency level data.

This survey will be repeated approximately every 2 to 4 years, as described in section 108 of FSMA

(NAFDS), for the purpose of monitoring progress in food and agricultural defense by government agencies.

A purposive sampling strategy will be employed, such that the government agencies participating in food and agricultural defense cooperative agreements with FDA (22 State Agencies) and USDA (27 State Agencies) will be asked to respond to the voluntary survey. Food defense leaders responsible for conducting food defense activities during a food emergency for their jurisdiction will be identified and will receive an emailed invitation to complete the survey online; they will be provided with a web link to the survey. The survey will be conducted electronically on the *FDA.gov* web portal, and results will be analyzed by the interagency working group.

In the **Federal Register** of March 28, 2018 (83 FR 13284), we published a notice inviting public comment on the proposed collection of information. Although one comment was received, it was not responsive to the four collection of information topics solicited and therefore will not be discussed in this document.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
State Survey	49	1	49	0.33 (20 minutes)	16.17

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

The total burden for this collection of information, therefore, is 16.17 hours.

The FDA Office of Partnerships reviewed the questionnaire and provided the amount of time to complete the survey. The total burden is based on our previous experiences conducting surveys.

Dated: June 26, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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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 July 30, 2018.

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.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, *PRStaff@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

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. We 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 color additives used in animal food. Animal owners use the information to become knowledgeable

about the foods they purchase for their animals. Color additive information enables a consumer to comparison shop and to avoid substances to which their animals may be sensitive.

Description of Respondents: Respondents to this collection of information are manufacturers of pet food products that contain color additives. In the **Federal Register** of February 20, 2018 (83 FR 7198), FDA published a 60-day notice requesting public comment on the proposed collection of information.

(Comment) One comment was received that supported FDA’s need for the information collection and characterized the burden of the information collection as low compared to the importance of informative food labels. The comment did not suggest revising our estimate of the burden. However, it suggested we should provide greater detail about how we estimated the number of respondents and the flow of new products.

(Response) We based our estimate of the number of respondents on the number of pet food manufacturers subject to this regulation. The figure of 3,120 used in table 1 was derived from the number of establishments listed under North American Industrial Classification System codes 311111 and 311119, including very small establishments. As noted in the 60-day notice, we based our estimate of the flow of new products on A.C. Nielsen data for the number of animal food product units for sale (for which sales of the products are greater than zero) in the latest year for which data is available, stated to be 25,874. Then, we assumed that the flow of new products would be 10 percent per year, for a figure of 2,587 new products per year. That figure was used in table 1 as our estimate of the total annual disclosures. FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN ¹

21 CFR Section/activity	Number of respondents	Number 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	0.8292	2,587	0.25 (15 minutes)	647

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

The requirement became effective November 18, 2013; thus, we estimate 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, we estimate 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 become available on the market each year. We also estimate that there are approximately 3,120 manufacturers of pet food subject to either § 501.22(k)(1) or (2). Assuming the approximately 2,587 new products are split equally among the firms, then each firm would prepare labels for approximately 0.8292 new products per year (2,587 new products—3,120 firms is approximately 0.8292 labels per firm). We expect 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, we estimate 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). The burden for this information collection has not changed since the last OMB approval.

Dated: June 26, 2018.
Leslie Kux,
Associate Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-2398]

Development of Non-Traditional Therapies for Bacterial Infections; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled “Development of Non-Traditional Therapies for Bacterial Infections.” The purpose of the public workshop is to discuss the general development considerations of non-traditional therapies, including pre-clinical development, early clinical studies, and phase 3 clinical trial designs to evaluate safety and efficacy.

DATES: The public workshop will be held on August 21, 2018, from 8:30 a.m. to 4:30 p.m. and August 22, 2018, from