to a state Medicaid agency that informs the agency of the time and place of the hearing, and the issues to be considered. If we subsequently notify the agency of additional issues that will be considered at the hearing, we will also publish that notice.

Any individual or group that wants to participate in the hearing as a party must petition the presiding officer within 15 days after publication of this notice, in accordance with the requirements contained at 42 CFR 430.76(b)(2). Any interested person or organization that wants to participate as *amicus curiae* must petition the presiding officer before the hearing begins in accordance with the requirements contained at 42 CFR 430.76(c). If the hearing is later rescheduled, the presiding officer will notify all participants.

The notice to Texas announcing an administrative hearing to reconsider the disapproval of its SPA reads as follows:

Ms. Kay Ghahremani
State Medicaid/CHIP Director
Health and Human Services Commission
Post Office Box 13247
Mail Code H100
Austin, TX 78711

Dear Ms. Ghahremani:

I am responding to your request for reconsideration of the decision to disapprove Texas' State Plan amendment (SPA) 14–25, which was submitted to the Centers for Medicare & Medicaid Services (CMS) on August 26, 2014, and disapproved on April 7, 2015. I am scheduling a hearing on your request for reconsideration to be held on August 6, 2015, at the Department of Health and Human Services, Centers for Medicare & Medicaid Services, Division of Medicaid & Children's Health, Dallas Regional Office, 1301 Young Street, Room 714, Dallas, TX 75202.

I am designating Mr. Benjamin R. Cohen as the presiding officer. If these arrangements present any problems, please contact Mr. Cohen at (410) 786–3169. In order to facilitate any communication that may be necessary between the parties prior to the hearing, please notify the presiding officer to indicate acceptability of the hearing date that has been scheduled and provide names of the individuals who will represent the State at the hearing. If the hearing date is not acceptable, Mr. Cohen can set another date mutually agreeable to the parties. The hearing will be governed by the procedures prescribed by federal regulations at 42 CFR part 430.

In part, this SPA requested CMS approval to revise the methodology for calculating the hospital-specific limit for the Disproportionate Share Hospital (DSH) program. Specifically, SPA 14–25 proposed to exclude from the calculation, the portion of a Medicare payment for an individual who is dually-eligible for Medicare and Medicaid that exceeds the Medicaid allowable cost for the service provided to the recipient. This exclusion would permit the state to make Medicaid DSH payments that are above and beyond hospitals' reported uncompensated costs of providing services to Medicaid and uninsured individuals.

The issue to be considered at the hearing is:

• Whether Texas SPA 14–25 is inconsistent with Medicaid DSH requirements at sections 1902(a)(13)(A)(iv) and 1923 of the Social Security Act (Act) because it would provide for payment to disproportionate share hospitals of amounts that exceed the hospital's uncompensated costs which cannot be considered consistent with DSH requirements pursuant to the hospital-specific limit under section 1923(g)(1) of the Act.

In the event that CMS and the State come to agreement on resolution of the issues which formed the basis for disapproval, this SPA may be moved to approval prior to the scheduled hearing. I am responding to your request for reconsideration of the decision to disapprove Texas' Medicaid state plan amendment (SPA) 14–025, which was submitted to the Centers for Medicare and Medicaid Services (CMS) on August 26, 2014, and disapproved on April 7, 2015. I am scheduling a hearing on your request for reconsideration to be held on August 6, 2015, at the Department of Health and Human Services, Centers for Medicare and Medicaid Services, Division of Medicaid & Children's Health, Dallas Regional Office, 1301 Young Street, Room 714, Dallas, TX 75202.

Sincerely,

Andrew M. Slavitt

cc: Benjamin R. Cohen

Section 1116 of the Social Security Act (42 U.S.C. 1316; 42 CFR 430.18) (Catalog of Federal Domestic Assistance program No. 13.714. Medicaid Assistance Program.)

Dated: June 24, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2015–16098 Filed 6–29–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0161]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Export Certificates for Food and Drug Administration Regulated Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled, ''Export Certificates for FDA Regulated Products'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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: On February 10, 2015, the Agency submitted a proposed collection of information entitled, ''Export Certificates for FDA Regulated Products'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0498. The approval expires on March 31, 2018. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: June 25, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–16023 Filed 6–29–15; 8:45 am]

BILLING CODE 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 July 30, 2015.

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	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 make 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.

[FR Doc. 2015–16022 Filed 6–29–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–2126]

Agency Information Collection Activities; Proposed Collection; Comment Request; Evaluation of the Food and Drug Administration's Campaign To Reduce Tobacco Use Among Lesbian, Gay, Bisexual, and Transgender Young Adults

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 a notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on